THE INTERNATIONAL CENTRE FOR THE SETTLEMENT OF INVESTMENT DISPUTES

In the Matter of Arbitration Between: APOTEX HOLDINGS INC. and APOTEX INC., Claimants, and THE UNITED STATES OF AMERICA, Respondent.	Case No. ARB(AF)12/1 (Revised) Volume 5

HEARING ON JURISDICTION AND THE MERITS

Friday, November 22, 2013

The World Bank
1225 Connecticut Avenue, N.W.
C Building
Conference Room C8-150
Washington, D.C. 20433

The hearing in the above-entitled matter came on, pursuant to notice, at 8:01 a.m. before:

MR. V.V. VEEDER, QC, President

MR. J. WILLIAM ROWLEY, QC, Arbitrator

MR. JOHN R. CROOK, Arbitrator

Also Present:

MR. MONTY TAYLOR
Secretary to the Tribunal

MS. MARTINA POLASEK
Alternate Secretary of the Tribunal

Court Reporter:

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C O N T E N T S

PAGE

PRELIMINARY MATTERS

OPENING STATEMENTS

ON BEHALF OF THE RESPONDENT:

Res Judicata (con't)
NAFTA Article 1139(g) 1211
By Ms. Thornton

NAFTA Article 1139(h)
By Mr. Sharpe 1248

NAFTA Article 1101(1) 1282
By Mr. Sharpe

Overview of Relevant Facts 1327
By Ms. Cate

NAFTA Articles 1102 and 1103
By Mr. Bergman 1386

Article 1105
By Mr. Blanck 1451

U.S.-Jamaica BIT
By Mr. Bigge 1522

CONFIDENTIAL PORTIONS

PAGE
1. 1246-1248
2. 1266
3. 1327-1386
4. 1446-1447
5. 1497-1507

P R O C E E D I N G S

PRESIDENT VEEDER: Good morning, ladies and gentlemen. We'll start Day 5 of this hearing, Friday, November 22. I'm just going to ask the Secretary to read out the timings from yesterday.

SECRETARY TAYLOR: For Day 4, the Tribunal had 11 minutes, 42 seconds for housekeeping and procedural matters. For the Respondent's Case-in-Chief, 29 minutes, 44 seconds. The examination of Dr. Carmelo Rosa, there were 26 minutes, 45 for the Respondent; 3 hours, 27 minutes and 14 seconds for the Claimants; and 50 minutes and 21 seconds for the Tribunal.

For the examination of Mr. William Vodra, the Respondent had 35 minutes, 26 seconds; the Claimants, 51 minutes, 1 second; the Tribunal, 8 minutes, 51 seconds.

In more detail on the examinations, for Dr. Carmelo Rosa, cross-examination was 3 hours, 27 minutes and 14 seconds; redirect examination was 26 minutes, 45 seconds; the Tribunal 50 minutes, 21 seconds. And for the examination of Mr. William

08:01:48 Vodra, direct examination was 27 minutes, 31 seconds; cross-examination, 51 minutes, 1 second; redirect examination, 7 minutes, 55 seconds; Tribunal, 8 minutes, 51 seconds.

For a total of 4 hours, 18 minutes, and 15 seconds for the Claimants on Day 4; 1 hour, 31 minutes, 55 seconds, for the Respondent; 1 hour, 10 minutes, 54 seconds for the Tribunal, for a total of 7 hours, 1 minute, 4 seconds on Day 4.

And in terms of time remaining, the Respondents have used 4 hours, 14 minutes, and 1 second of their 11 hours and 45 minutes as agreed between the Parties, which leaves 7 hours 30 minutes 59 seconds left.

PRESIDENT VEEDER: Are there any housekeeping matters we need to address? We ask the Claimants first.

MR. LEGUM: Just one very minor matter, Mr. President.

During Ms. Grosh's argument--I suppose yesterday, she made reference to a slide that we'd projected concerning Grand River. We've now gone back

08:02:58 and checked that slide, and, in fact, there was an error on the slide. There should have been ellipses where there were none. We do cite check our slides, but cite checks are not as effective when done by sleep-deprived lawyers at 3:00 in the morning than when they are done at other times of the day. We apologize for this error on our part, and we will provide a corrected slide.

PRESIDENT VEEDER: Well, there is no need for an apology. I think you've done magnificently so far to assist the Tribunal and both sides, and we know the pressure that advocates are under. Thank you for that.

Anything else from the Claimant?

MR. LEGUM: I would simply suggest that, perhaps, going forward the Parties can consult on any errors that are in slides.

PRESIDENT VEEDER: Of course.

MR. LEGUM: Obviously, they're on both sides, and we can work towards making sure the Tribunal has what it needs that is most accurate as it goes into deliberations.

08:03:47 PRESIDENT VEEDER: Thank you. And on the Respondent's side, any housekeeping?

MS. GROSH: No, Mr. President. Thank you.

PRESIDENT VEEDER: Let's resume the submissions from last night. Thank you.

CONTINUED PRESENTATION-IN-CHIEF BY COUNSEL FOR RESPONDENT

MS. THORNTON: Okay. I will pick up where we left off yesterday and continue our discussion of the res judicata effect of the Apotex I and II Award. I will begin by walking the Tribunal through the record in the previous arbitration to show that the jurisdictional issue of Apotex Inc.'s ANDAs as investments was fully arbitrated and determined in that Award.

In the previous proceeding, the United States observed that Apotex's ANDAs for the two drugs involved were only tentatively approved by the FDA. In response, Apotex argued that the approval status of its ANDAs was immaterial and that its ANDAs were actualized the moment they were filed with FDA. Specifically, Apotex Inc. represented that the

1212

approval status and ongoing regulation of Apotex's ANDAs is irrelevant to the issue of whether ANDAs constitute the property of Apotex. Apotex's investment in its ANDAs and its property rights therein are actualized the moment such ANDAs are filed with FDA.

Apotex asserts that the United States has erred and that Apotex never conceded that the distinction between a tentatively and a finally approved ANDA was a distinction without a difference. The United States made no error. In its Rejoinder on Objections to Jurisdiction filed in the previous case, Apotex Inc. stated unequivocally that "Respondent's distinctions between tentatively approved ANDAs and finally approved ANDAs are distinctions without a difference. Regardless of whether an ANDA is tentatively approved, finally approved, or is still under substantive review by the FDA, the ANDA is the exclusive property of the ANDA applicant that has been acquired for and/or is expected to be used for the purpose of economic benefit or other business purposes."

1213

In the interests of time, I will not read the text on the next slide, but Apotex continued to make this point repeatedly in its filings in the previous arbitration.

The Parties' arguments concerning the approval status of Apotex Inc.'s ANDAs were tested by the Tribunal during the Apotex I and II hearing. On the first day, President Landau observed the focus placed by the United States on the ANDAs being tentative and not finalized or approved. He asked pointedly, "What would be the United States's position if the ANDA was approved, a final ANDA. Would that be property or not?"

The United States responded that "Even a finally approved ANDA would not be property, and the reason is that the FDA retains discretion by law to revoke approval of even a finally approved ANDA for any of the number of stated reasons that are up on the slide without any payment of compensation. There has been no evidence adduced, as I'll discuss momentarily that United States's law recognizes even an approved ANDA as a property right."

1214

President Landau continued pressing the United States as to whether an ANDA did not constitute property because it might be revoked. In response, the United States answered that "One of the principal tenets of property would be exclusivity, and yet FDA has the discretion by law to decline to approve or even revoke an ANDA, even a finally approved ANDA. So, we have not seen any evidence of how a person could claim a property right in something when the Government entity has discretion by law to revoke that without giving any property-like remedies to the applicant."

On Day 2 of the hearing, Apotex addressed the issue of approval status in the context of whether an ANDA is acquired in the expectation or used for the purpose of economic benefit our other business purposes as required by NAFTA Article 1139(g). Apotex stated that "Now the Government appears to want to make some very fine lines and cuts as to what it means to be acquired. Is it acquired when you first put it together? Is it acquired when you file it with the FDA, when you get final approval? We would submit

1215

that that really doesn't matter. And, in fact, an ANDA, in the strictest sense of the term, is acquired once you put it together, once you prepare it, and you have it. It has now become an asset in investment, and again with the future expectation of economic benefit. So, no matter what definition of acquired you're using here, we submit it's satisfied."

Also on Day 2, Apotex revisited the issue of approval status in the context of discussing the revocability of the ANDAs. "If I could go just back real quick to the FDA approval revocation issue, we think that this is a bit of a red herring argument. It is nice for the Government to point out that there are all these reasons why an ANDA could be invoked"--I think they meant "revoked" there--"or why it might not get approval, but those aren't the facts here. It is undisputed these ANDAs were approvable. So, there is no reason for this panel to look behind this FDA regulatory scheme and say, well, that ANDA approval could have been revoked. The fact of the matter was it wasn't. Apotex got timely tentative approval, then they got their final approval. So, there was no

revocation, there were no issues here, so we don't think that that's a basis to say that somehow this is not property."

Apotex, of course, now wishes that it could retract the legal arguments it previously made in litigating the issue, but it cannot wish those arguments out of existence.

The Tribunal's jurisdictional Award considered all of these arguments briefed and litigated by the Parties in reaching the determination that Apotex Inc.'s ANDAs did not constitute an investment under Article 1139. Specifically, Paragraphs 157, 177, and 227 of the Apotex I and II Award, the Tribunal detailed three aspects of Apotex Inc.'s alleged investments, two of which concern us here. Those are the ANDAs as property under Article 1139(g) and the commitment of capital and resources into the territory of the United States in connection with its ANDAs under Article 1139(h).

The Tribunal's overall conclusion, as stated in Paragraph 241 of the Award, was that "No investment has been made by Apotex in the territory of the United

States within the scope of NAFTA Chapter 11."

Ultimately--and this is critical--the Tribunal concluded that Apotex's activities were "those of an exporter, not an investor," and ultimately held that "Apotex, like any company that intends to export generic drug products to the United States for sale in the U.S. market, sought regulatory approval from the FDA through the submission of ANDAs. But this process cannot change the nature of the underlying activity, or constitute an "investment" in and of itself, within the meaning and scope of the NAFTA Article 1139."

The Tribunal's determination with respect to Article 1139(g) turned not on whether ANDAs could be construed as property, their alleged exclusivity, or their approval status with FDA--although it carefully considered the arguments from both Parties, as I will show in the next presentation--rather, the Tribunal's holding turned on the inherent nature of the ANDAs as applications to export generic drugs for sale by others in the United States.

I'll highlight two critical passage of the

Tribunal's reasoning that illustrate this. First, in Paragraph 217 of the Award, the Apotex I and II Tribunal stated that "Whilst an ANDA itself may not be, in strict technical terms, an export or import license, it operated--in this case--in precisely the same way. As already noted, all Apotex's operations were outside the U.S. Apotex wanted to export its goods to the U.S. to be marketed and sold there by other entities. In order to do this, Apotex was required to obtain permission, which was to be secured by the submission of an ANDA. The ANDA was, thus, a requirement in order to conduct an export business. If there had been no ANDA process, the underlying business could not be said to be an investment in the U.S. The fact that an ANDA was require does not change the nature of the business."

Second, in Paragraphs 224 and 225, the Tribunal held that "Apotex's submissions as to the notion and general characteristics of property...are of only limited assistance in delimiting NAFTA Article 1139(g). The jurisdictional issue here turns upon the inherent nature of the relevant ANDAs, not

the nature of Apotex's rights over them...neither Apotex's ANDAs nor its activities in Canada nor the costs incurred there in meeting the requirements of the U.S. regulatory regime for exporting its goods, are investments in the United States."

The inherent nature of Apotex's finally approved ANDAs is no different from the inherent nature of its filed or tentatively approved ANDAs. They are all simply applications for revocable permission to export drugs to the United States for sale by others. So, even if they could be construed as property, a final ANDA facilitates the same underlying activity, the export and cross-border sale of drugs.

Just a quick word on the Apotex I and II Tribunal's determination with respect to Article 1139(h), because Mr. Sharpe will return to this in more detail later. Counsel for Apotex suggested on Monday that the Apotex I and II Award is not res judicata with respect to Apotex's alleged investment under Article 1139(h) because Apotex's arguments in the previous case were undeveloped.

That's Day 1, Page 196.

But Apotex cannot avoid the res judicata effect of the Award for two reasons. First, as President Veeder pointed out, the Apotex I and II Tribunal conducted a fairly careful analysis of Apotex's possible case under 1139(h). In fact, the Tribunal considered and rejected several of the theories Apotex now advances.

Second, as the United States pointed out in our Rejoinder, citing authorities, issue estoppel precludes relitigation of the entire issue, not simply arguments raised in connection with that issue in the prior case. Indeed, President Veeder asked yesterday whether Apotex Inc. could have made--sorry, probably Wednesday--could have made the same arguments it now makes with respect to Article 1139(h). And that's Page 555 of the transcript.

In response, Apotex's counsel replied that there were two significant differences: Namely, the distinction between tentatively and finally approved ANDAs, and the fact that Apotex Holdings has been added as a Claimant. That's Page 556 of the

transcript.

Both of these alleged distinctions have already been dealt with. Apotex points to no critical new fact or subsequent event that would provide a basis to relitigate this issue. Apotex Inc. had finally approved ANDAs when it brought its previous claims, and there is no suggestion that Apotex Holdings could not have been a Claimant in the previous arbitration.

To sum up this portion of my presentation, I want to emphasize that there is nothing radical or even novel about the United States's approach. As the United States has shown, issue estoppel is a species of res judicata that has been recognized and applied by international courts and tribunals. Apotex's approach risks an inconsistent decision on the same issue with respect to the same Parties and the exact same Treaty provisions.

As the United States has explained, Apotex Inc.'s jurisdictional claim falls squarely within the ILA's Recommendations on Res Judicata and Arbitration. The Parties are the same. A key jurisdictional issue

involving the same provisions of the NAFTA is the same. That issue was fully arbitrated and determined in the Apotex I and II Award, and the Award was final and binding.

Recognizing the preclusive effect of the Apotex I and II Award would also serve to protect the Respondent against future vexatious claims, not a speculative concern. This is Apotex's third NAFTA claim against the United States, and these claims have been a drain on public resources.

In dismissing Apotex's claims in the previous arbitration, the Tribunal found that the United States ought never have been embroiled in this process. The same is true here. A finding of res judicata would preclude any more frivolous claims that rest upon Apotex Inc.'s alleged status as an investor through its ANDAs.

Finally, precluding Apotex Inc.'s jurisdictional claim would also serve the primary objective of res judicata: Ensuring finality of litigation. As President Veeder elsewhere observed, "Just as it would be absurd for the Parties to

relitigate the same dispute time and again, like Sisyphus or the hero in Groundhog Day, would it not be equally absurd for Parties to relitigate the issues in a different arbitration where those same issues have already been decided in the reasons for an earlier Award between the same Parties?"

It is precisely this absurdity that the United States seeks to avoid. We, therefore, ask the Tribunal to find that the Apotex I and II Award, which involved the same Parties, litigated the exact same jurisdictional issue, and involved the exact same NAFTA provisions, is res judicata for these proceedings.

Thank you. This concludes our remarks on res judicata. Unless there are questions, I can continue on with our presentation on Article 1139(g).

PRESIDENT VEEDER: One question.

ARBITRATOR CROOK: Quick question. Counsel for Apotex suggested earlier--I'm sorry; I don't have the page cite--that we ought to disregard Orinoco Steamship because it didn't involve the application of international law.

Do you have any comments on that?

MS. THORNTON: Just that the Amco v. Indonesia decision that we also discussed cited the very same application of res judicata as in the Orinoco Steamship case, and they were applying international as well as Indonesian law.

ARBITRATOR CROOK: Thank you.

PRESIDENT VEEDER: We have no further questions at this stage. Thank you for that.

MS. THORNTON: I will continue the United States's jurisdictional objections by addressing Apotex Inc.'s claim that its Abbreviated New Drug Applications, or ANDAs, constitute "investments" in the United States under Article 1139(g). My presentation will proceed in two parts. The first part will address the arguments raised by Apotex common to both the previous and current arbitrations and the previous Tribunal's reasoning in rejecting those arguments. The second part will explain why none of Apotex's new arguments advance Apotex's jurisdictional claim. My remarks will take just over a half hour; after which, my colleague, Mr. Sharpe,

will explain why Apotex Inc.'s ANDAs are not "interests arising from the commitment of capital or other resources" and, consequently, not "investments" under Article 1139(h).

In this proceeding, as in the previous one, Apotex contends that its ANDAs fall within the definition of "investment" in Article 1139(g) as "intangible property." Article 1139(g) defines "investment" as including "real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes."

To fall within the purview of Article 1139, however, Apotex Inc. must make an investment in the territory of another NAFTA State, not one's own. This is not a disputed point and has been noted by successive NAFTA Tribunals such as Bayview, Canadian Cattlemen, Grand River, and most recently Apotex I and II. And, of course, the Apotex I and II Tribunal concluded that Apotex Inc.'s ANDAs are not "property" in the United States for purposes of Article 1139(g). To the contrary, for companies such as Apotex Inc.

whose manufacturing facilities are outside the United States, an ANDA is "simply an application for revocable permission to...export a product for sale by others in the United States."

This first half of my presentation will rebut the four arguments raised by Apotex that were considered and all rejected by the Apotex I and II Tribunal.

First, Apotex argues that "FDA's own regulations recognize that a pharmaceutical company may own an ANDA, and that it may be transferred for consideration." In the previous proceeding, Apotex likewise argued that "an ANDA applicant owns its ANDA," and that "FDA regulations explicitly state that...only the applicant may transfer ownership of its application."

But ownership, the Apotex I and II Tribunal concluded, is not enough to establish an ANDA as "property" for purposes of Article 1139(g). In rejecting Apotex's argument, the Tribunal concluded that "Even if, as a technical matter, the application may be owned, unlike Apotex's approach, the Tribunal

does not consider that NAFTA Article 1139(g) can be approached by divorcing the concept of property from its context, and applying it in the abstract."

"The fact that only the applicant may transfer ownership of its application"--in the words of the Apotex I and II Tribunal--"cannot transform the application into property for purposes of NAFTA Chapter 11." Ownership is insufficient to render an ANDA property for purposes of Article 1139(g).

Second, Apotex argues that ANDAs are regularly bought and sold. In the previous arbitration, Apotex similarly argued that an ANDA can be bought and sold like all other property. But the Apotex I and II Tribunal held that "Even if an ANDA may be bought and sold, as Apotex argues, this would still not change its essential character, which is an application to (in this case) export generic drugs into the United States."

So it is clear that the ability to buy and sell an ANDA also is insufficient for an ANDA to fall within Article 1139(g).

Third, Apotex argues that "the right to

1228

market a drug under an approved ANDA is, itself, a protected property right, and so is the statutory exclusivity period afforded some ANDA holders." Previously, Apotex similarly argued that an ANDA applicant has the exclusive right to possess, use, and enjoy the ANDA. Apotex's arguments concerning alleged exclusivity were also rejected by the Apotex I and II Tribunal, which held that "Even if Apotex has exclusive rights over the ANDA, this cannot change the inherent nature of the ANDA itself. In other words, an application to export generic drugs into the United States is not transformed into an 'investment' for the purposes of NAFTA Chapter 11 because the holder of the application has exclusive rights thereto."

According to the Tribunal, Apotex's alleged exclusivity was open to question in any event. This is because, as noted by the Apotex I and II Tribunal, "FDA may revoke tentative approval, or even final approval, of ANDAs for a variety of reasons related to the new products' safety and effectiveness, including a finding that there is an imminent hazard to public health; that clinical or other tests or scientific

1229

data indicate any lack of safety; or a lack of substantial evidence from adequate and well controlled investigations that the drug will have the effect it is reported or represented to have."

The Tribunal further noted that federal regulations in the United States expressly afford the FDA a broad discretion in revoking tentative or even final approval of ANDAs. Those regulations are cited in Paragraph 57 of our Counter-Memorial, where we explained that FDA may revoke final ANDA approvals for a variety of reasons, including for a failure to comply with cGMP regulations.

Apotex's ANDAs in the United States were, thus, "at all times entirely subject to the exercise of FDA's regulatory power." Apotex does not dispute this. As noted by the Apotex I and II Tribunal, "Even when finally approved, Apotex was not protected from changes to, or revocation of, its ANDAs."

It is therefore clear that the Apotex I and II Tribunal considered the argument about alleged exclusivity, including of final ANDAs, to be unavailing. Apotex's counsel suggests that the U.S.

1230

position on this proves too much because any property interest can, theoretically, be revoked. This is Page 184 of the transcript. But where an interest rises to the level of a legally cognizable property interest, revocation typically entitles holders to property-like remedies, such as compensation. I will return to this point a little later in my presentation.

Fourth, Apotex argues that its ANDAs constitute property "in the United States" because they "are regulated by U.S. law." Apotex cites Bayview for the proposition that a "salient characteristic of an investment will be that the investment is primarily regulated by the law of a State other than the State of the investor's nationality."

In its previous claims, Apotex similarly cited Bayview for the proposition that because Apotex made "an investment that falls under the laws and jurisdiction of the authorities of another NAFTA Party, it should be treated as a foreign investor."

Again, the Apotex I and II Tribunal rejected

1231

the Apotex's argument holding that "The mere regulation of Apotex's foreign products (however extensive) cannot transform the costs incurred in developing those products into investments in the United States."

In this vein, the Tribunal concluded that regulatory costs expended in the preparation and filing of ANDAs were no more than an exercise in securing regulatory clearance and do not fall within the scope of NAFTA Article 1139, nor do they change the inherent nature of the activity for which clearance is sought.

As the Grand River Tribunal recognized, "Where a company must meet regulatory requirements to sell its products in the United States, the costs of such compliance themselves are not investments." Rather, those costs are "incident to commercial Contracts for the sale of goods or services, which fall outside of Article 1139's definition of investment."

If such costs could be deemed "investments," the Apotex I and II Tribunal explained that "Any

1232

08:29:53 Canadian or Mexican exporter requiring U.S. regulatory clearance to have its goods sold by third parties in the United States could potentially bring an investment claim under NAFTA Chapter 11 whenever such clearance, in the exporter's view, was wrongly denied or delayed."

Accordingly, and quite rightly in the United States's view, the Apotex I and II Tribunal concluded that "Allowing a mere application for regulatory clearance to export goods into the United States to give rise to an 'investment' claim under Chapter 11 would be inconsistent with the core objectives of NAFTA's investment chapter."

So, the mere fact that Apotex Inc.'s ANDAs are regulated by U.S. law does not make them investments in the United States. In sum, the Apotex I and II Tribunal considered many of the very same arguments raised by Apotex here in the previous proceeding and rejected them all. As that Tribunal observed, "Unlike Apotex's approach, the Tribunal does not consider that NAFTA Article 1139(g) can be approached by divorcing the concept of 'property' from

1233

08:31:07 its context, and applying it in the abstract."

The Tribunal found that general notions and characteristics of "property" were of limited value in determining the meaning of what constitutes an "investment" under Article 1139(g). Rather, as I showed before, "The jurisdictional issue here turns upon the inherent nature of the relevant ANDAs, not the nature of Apotex's rights over them. As set out above, even assuming that the ANDAs were Apotex's exclusive 'property,' they remain no more than applications for permission to (in this case) export, and, as such, neither fell within NAFTA Article 1139(g) nor constituted 'investments' as contemplated more generally by NAFTA Chapter 11."

For all the same reasons as stated by the Apotex I and II Tribunal, this Tribunal also should reject Apotex Inc.'s arguments that its ANDAs fall within the scope of Article 1139(g).

The second half of my presentation will refute the four new arguments that Apotex Inc. has raised in this arbitration in an attempt to strengthen its claim that its drug applications constitute

1234

08:32:20 intangible property under Article 1139(g). None of these new arguments advances its case.

Apotex's first new argument places heavy reliance on NAFTA Article 1110(7) which states, "This article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights or to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with Chapter 17" on intellectual property.

Apotex extrapolates from this provision that "revocable intangible rights are investments that give rise to obligations under the NAFTA investment chapter" and, ergo, its ANDAs must also be investments.

Chapter 17 of the NAFTA requires the Parties to provide certain protection to well-established intellectual property rights such as patent, copyright, and trademarks. Of course, it makes logical sense that in the Framework of the NAFTA, the United States would promote intellectual property and seek to harmonize the protections with those provided

1235

08:33:36 by U.S. law. Although Apotex has questioned the relevance of U.S. law, its arguments have repeatedly relied on U.S. law, and Apotex Inc. acknowledged in the previous arbitration that "U.S. law is informative in defining 'property' because it is the law of the host State."

International law does not define property, and the NAFTA does not otherwise define what constitutes intangible property for purposes of Article 1139(g). It is, therefore, appropriate to examine U.S. law on this issue.

Patents, copyrights, and trademarks have long been established, recognized, and protected as property by U.S. law. Apotex has shown no case law demonstrating that ANDAs are recognized as property under U.S. law. Its revocable ANDAs are contingent interests of the kind NAFTA Tribunals have routinely declined to recognize as property.

On Monday, reversing its position in the previous arbitration, Apotex asserted that its tentatively approved ANDAs were contingent interests. In contrast, it alleges that its finally approved

08:34:51 ANDAs are vested rights. This is Page 176 of the transcript. But allegations are not evidence. In both its written submissions and at this hearing, Apotex fails to cite any factual evidence or Legal Authority in support of its position. In contrast, the United States has demonstrated repeatedly that there is no legally cognizable property interest or vested right in revocable permits. A consistent line of jurisprudence on this point dates from Dames and Moore to the present and is summarized on the slide.

For these reasons, Apotex's conclusion that because some intangible intellectual property rights such as patents or copyrights may be considered investments for purposes of the NAFTA, its drug applications are also investments is a non sequitur. NAFTA Article 1110(7) simply does not define which intangible property rights are investments and which are not.

Turning to Apotex's second new argument Apotex's refers to Article 1108(1)(a)(i), a provision which "permits limited exceptions to certain protections of Chapter 11 (such as National Treatment

08:36:15 and MFN Treatment) for certain Measures listed in Annexes to the NAFTA."

Apotex further notes that the United States's schedule to Annex 1 excludes from Article 1102 revocable licenses granted under the U.S. Atomic Energy Act. Apotex thus concludes that Chapter 11 contemplates that revocable licenses may be "investments" and, ergo, that its ANDAs must be "investments."

Again, Apotex's reasoning is flawed. Article 1102 requires National Treatment with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments. A license may be required for the establishment or conduct of an investment. A reservation means that the United States may discriminate on the basis of nationality when granting these licenses. A reservation allowing the United States to deny such licenses, however, does not necessarily mean that the licenses themselves are investments.

Apotex's first example concerns a mandatory,

08:37:30 revocable commercial license for nuclear reactors and production facilities in the United States. Its second example concerns a revocable customs broker's license. Both licenses are necessary for the establishment and conduct of investments, and both reserved Measures are discriminatory, as non-U.S. nationals cannot obtain them. It was, thus, logical for the United States to exclude these regimes from a nondiscrimination provision such as Article 1102. That exclusion does not mean that revocable licenses themselves constitute investments under Article 1139(g).

Consistent with the U.S. view, the Apotex I and II Tribunal described ANDAs not as investments, but akin to revocable export or import licenses to conduct its trade activity. This is Paragraph 217 of the Award I discussed earlier and shown again on the slide. "Whilst an ANDA itself may not be, in strict technical terms, an export or import license, it operated, in this case, in precisely the same way. As already noted, all Apotex's operations were outside the U.S. Apotex wanted to export its goods to the

08:38:45 U.S., to be marketed and sold there by other entities. In order to do, this Apotex was required to obtain permission, which was to be secured by the submission of an ANDA. The ANDA was, thus, a requirement in order to conduct an export business."

Now, I want to take a minute to address a question posed by Mr. Rowley on Monday. Mr. Rowley asked whether an approved ANDA in the hands of a U.S.-based pharmaceutical manufacturer might be an investment while it would not be in the hands of a foreign manufacturer. That's Page 187 of the transcript.

So, to bring a claim under the NAFTA, one has to be a qualifying investor. So we assume under this hypothetical that the U.S.-based pharmaceutical manufacturer is owned or controlled by a foreign investor of another NAFTA Party. It has a pharmaceutical manufacturing facility in the United States that would constitute an investment. This U.S.-based pharmaceutical manufacturer submits an ANDA for FDA approval--let's say it's specific to the facility in the United States. In our view, that ANDA

1240

is still only revocable permission to manufacture and market a drug. It is not property and would not constitute an investment in and of itself.

Next, I want to briefly close the loop on the Parties' discussion of the takings and due process clauses of the United States Constitution. According to Apotex, the United States must explain why takings clause jurisprudence--which Apotex asserts is more limited with respect to defining "property"--is more relevant than due process clause jurisprudence. Of course, it is not the Respondent's burden to do so. Apotex is the Claimant and must demonstrate the opposite.

But, even under the due process clause, Apotex's argument is without merit. In B-west Imports, the U.S. Court of Appeals for the Federal Circuit explained that a ban on Chinese firearm permits could give rise neither to a takings nor a due process claim.

In connection with the due process claim, the Court explained that "The appellants' due process claim fares no better. They assert that the

1241

implementation of the Chinese arms embargo deprived them of property without due process of law by denying them the opportunity to sell in the United States the munitions for which they had obtained permits prior to the announcement of the embargo. As we have discussed, however, the appellants' right to import and sell Chinese arms in the United States was subject at all times to the hazard that their permits would be revoked, pursuant to statute and regulation, on foreign policy grounds or for other reasons. The due process clause does not require the Government to stand as a surety against the adverse consequences sometimes suffered by persons who knowingly undertake that kind of commercial risk."

And as discussed in our Rejoinder, there is no "right to import" goods, including generic drugs, into the United States. As held by the Supreme Court as early as 1904, "No individual has a vested right to trade with foreign nations which is so broad in character as to limit and restrict the power of Congress to determine what articles of merchandise may be imported into this country and the terms upon which

1242

a right to import may be exercised. This being true, it results that a statute which restrains the introduction of particular goods into the United States from considerations of public policy does not violate the due process clause of the Constitution."

In sum on this point, the Apotex I and II Tribunal recognized that Apotex's ANDAs operate like a revocable permit allowing its goods to be imported and sold by others in the United States. As such, and also for the reasons stated in the relevant jurisprudence, there is no "property right" that is protected either by the takings clause or the due process clause of the United States Constitution.

Apotex's third new argument in this arbitration is that because it has standing in U.S. courts with respect to its ANDAs, those ANDAs must be property rights for purposes of Article 1139. That is demonstrably untrue. The U.S. cases cited by Apotex merely recognize that an ANDA holder may have an interest from the outcome of litigation in the context of the relevant Statutory Framework (the so-called "Hatch-Waxman Amendments") that is sufficient to give

1243

the ANDA holder legal standing in court. The cases do not discuss ANDAs in terms of a legally cognizable property interest.

Standing is conferred on Parties with a variety of interests guaranteed by the U.S. Constitution by common law or by statute. That ANDA holders may have an interest in patent litigation, for example, is a matter regulated by statute (Hatch-Waxman) but does not prove that U.S. courts recognize an ANDA as property.

Apotex's fourth and final new argument in this case relies on an IRS memorandum describing ANDAs as "Government-granted rights" and recommending that ANDAs be considered intangible assets. The United States explained in its Counter-Memorial that benefits conferred by federal legislation may have some attributes of property under tax law, but that was insufficient to determine whether they constitute property protected by the Fifth Amendment.

Apotex's last filing also fails to address the points the United States made in its Rejoinder. There, the United States pointed to Apotex's admission

that it pays no tax in the United States on its ANDAs sales. During discovery, the United States requested Apotex Inc. to produce U.S. tax returns from 2008 to 2011 showing taxes paid on ANDA-related transactions. Apotex stated that "no documents responsive to this request exist." Apotex also asserted that nonpayment of U.S. taxes is immaterial to whether ANDAs constitute property. But Apotex misses the point. To fall within NAFTA Article 1139, the investment must be made in the United States. This is an argument the United States has consistently made. We didn't drop it, as Apotex contends. The fact that Apotex pays no U.S. taxes whatsoever on its ANDAs sales or any ANDA-related transactions goes to show that the situs of its ANDAs is Canada, not the United States.

Apotex's counsel offered an explanation as to why it had not paid U.S. taxes on a confirmed sale of an ANDA.

MR. LEGUM: Mr. President, just to be clear that we're not going to be discussing information in open session that was confidential.

MS. THORNTON: I was just about to get to

that.

MR. LEGUM: Thank you. I'm sorry. Please go ahead.

MS. THORNTON: I'm not going to raise names, is that--or any specifics about the transaction itself. Is that--or we can just go to closed session for a minute, if that's okay. Just to be safe.

PRESIDENT VEEDER: Probably safer to go into closed session. So let's go to closed session for about ten minutes. Thank you. We're now in closed session.

CONFIDENTIAL PORTION

MS. THORNTON: Thank you.

Mr. Crook asked whether the sale was a U.S. transaction or a Canadian one, to which Apotex only responded that neither Party was a U.S. entity. That's Page 574 of the transcript. That's literally all I'm going to say on the matter.

MR. LEGUM: We can go back to open session.

PRESIDENT VEEDER: Let's stop. It is better to be safe than sorry.

MS. THORNTON: So just finish the point?

PRESIDENT VEEDER: Just finish the point just in case.

MS. THORNTON: Apotex has had numerous opportunities in this arbitration to prove that its ANDAs constitute investments in the territory of the United States, and it has not done so. Apotex has failed to explain to the Tribunal why it should find a U.S. investment in an application prepared and apparently sited in Canada that involves no business operation in the United States and for which no U.S. taxes are paid.

In conclusion, none of Apotex Inc.'s arguments, old or new, support its contention that its ANDAs are intangible property constituting an investment in the territory of the United States. An ANDA application may be owned, transferred, or bought and sold, but that cannot change its essential character. As held by the Apotex I and II Tribunal, for companies such as Apotex Inc., whose manufacturing facilities are outside the United States, an ANDA remains no more than "an application for revocable permission to (in this case) export a product for sale (by others) in the United States."

Members of this Tribunal, that concludes our presentation on Article 1139(g). Unless you have questions, I would turn it over to Mr. Sharpe to address Article 1139(h).

PRESIDENT VEEDER: We have no questions. Let's go back into open session.

SECRETARY TAYLOR: Back in open session.

NONCONFIDENTIAL PORTION

MR. SHARPE: If we may, we're just loading the PowerPoint slides now. We'll be ready in just a minute.

PRESIDENT VEEDER: Of course.

MR. SHARPE: Thank you.

Actually, in light of the fact that we have a rather full day of presentations, perhaps I'll just get started and then we can catch up with the slides.

PRESIDENT VEEDER: We have the slides in our folders here.

MR. SHARPE: Right. Exactly.

So, Mr. President, Members of the Tribunal, whenever you're ready, I'll begin.

PRESIDENT VEEDER: Please continue.

MR. SHARPE: I will address Apotex's failure to establish an investment based on NAFTA Article 1139(h).

As we've discussed, and as in the slide in front of you, Article 1139(h) includes, under the definition of investment, "(h) interests arising from the commitment of capital or other resources in the

territory of a Party to economic activity in such territory such as under, (i), Contracts involving the presence of an investor's property in the territory of the Party, including turnkey or construction contracts or concessions or, (ii) Contracts where remuneration depends substantially on the production revenues or profits of an enterprise."

So Article 1139(h), thus, covers interests arising from the commitment of capital--commitment of capital other resources in the territory of a Party to economic activity in such territory, which, for purposes of this case, is the United States. Article 1139(h), of course, is not a freestanding provision. It's part of the broader definition of investment in Article 1139.

As the Apotex I and II Tribunal correctly recognized, Article 1139(h), "must be read with NAFTA Articles 1139(i) and (j), which clarify that investment does not mean (i) claims to money that arise solely from, (i), commercial contracts for sale of goods or services by a national or enterprise in the territory of a Party to an enterprise in the

territory of another Party, or, (ii), the extension of credit in connection with the commercial transaction, such as trade financing, other than a loan covered by subparagraph (d); or (j), any other claims to money that do not involve the kinds of interests set out in subparagraphs (a) through (h)."

The Apotex I and II Tribunal helpfully clarified the scope of Article 1139(h) by reference to the Mondev case. The Tribunal stated, in Apotex I and II, "By way of example, in Mondev v. United States, the Canadian Claimant alleged that through its wholly owned U.S. limited partnership, it obtained interests arising from contractual rights to develop large parcels of property in downtown Boston." The Tribunal, thus, concluded that through the rights acquired in these construction contracts, "Mondev's claims involved interests arising from the commitment of capital or other resources in the territory of the United States," which fell squarely within the definition of "investment" under NAFTA Article 1139(h).

This case, of course, is very different from

Mondev. Apotex does not claim any interests arising from contracts involving the presence of property in the United States such as a turnkey or construction contract, nor does Apotex claim any interests arising from Contracts where remuneration depends substantially on the production, revenues, or profits of an enterprise. Rather, as we've heard, Apotex Inc.'s only claim under Article 1139(h) is that its ANDA applications themselves "qualify as interests arising from the commitment of resources both within and without the United States to economic activity in the United States."

In particular, in its pleadings and in its statements this week, Apotex has made three arguments: One, Apotex's ANDAs are intangible property and, thus, separately constitute interests; two, Apotex's ANDAs are committed to economic activity in the territory of the United States; and, 3, Apotex's ANDAs, although prepared in Canada, reflect a commitment of resources in and into the United States.

The Apotex I and II Tribunal rejected all of these arguments confirming: One, that Apotex's ANDAs

1252

are not intangible property; two, the fact that ANDAs are committed to economic activity in the United States does not make them investments in the United States; and, three, the commitment of resources outside the United States does not establish an investment inside the United States.

Here, Apotex first argues that, for purposes of Article 1139(h), ANDAs are intangible property. Thus, separately constitute interests. As Ms. Thornton discussed, the Apotex I and II Tribunal considered and rejected Apotex's arguments in this regard. So I won't repeat those here.

I will note in its Rejoinder on Jurisdiction, Apotex expressed surprise that the United States had relied on the Apotex I and II Award on these points, "given that the Award made clear that arguments under Article 1139(h) before it were undeveloped," a point reiterated this week, despite the fact that Apotex had briefed the issue twice in its written submissions in the previous arbitration.

Here, Apotex quoted the Tribunal's statement that "In the course of its oral submission, Apotex

1253

then made clear that its submissions under NAFTA Article 1139(h) were to be treated as part of its submissions under NAFTA Article 1139(g) and not as independent grounds."

But Apotex's arguments essentially are no different in this case. Both cases argue for an overlap between Articles 1139(g) and (h). Here, Apotex argued in its Memorial--and this is at 395--"It is apparent that the Marketing Authorizations or ANDAs are an interest, as shown in the preceding subsection's discussion of ANDAs as property."

Apotex reiterated in its Reply, "Apotex's ANDAs represent interests for all the reasons stated in the preceding section and in the Memorial." The preceding section, II.A.1, is entitled "Apotex-Canada's ANDAs are Intangible Property Within the Meaning of Article 1139(g)."

The Apotex I and II Award addressed this argument as follows, which the President noted earlier this week: "In the course of its oral submissions, Apotex then made clear that its submissions under NAFTA Article 1139(h) were to be treated as part of

1254

its submissions under NAFTA Article 1139(g) and not as independent grounds."

This was specifically confirmed by the Tribunal:

"PRESIDENT LANDAU: ...The other point I just wanted to ask is, just for clarity, exact positioning of your Article 1139(h) case... that actually the Article 1139(h) argument, it doesn't stand by itself; is that right? It's dependent upon us making a finding that the ANDA itself is an investment?"

Members of the Tribunal, I understand that Apotex here is precisely asking that the Tribunal find that the ANDA itself is an investment and that it commits resources in and into the United States in support of that investment.

So, turning back to the slide, Apotex confirmed this point. "Yes. Our basic argument is it's part and parcel of the ANDA investment because the commitments that had been made, the commitments of capital"--it goes on--"it's hard to parcel out all the elements that go into this investment, but all these things go into it: The costs of development, the

1255

amount spent in the United States on the raw materials all go into the ANDA investment itself, and then obviously the substantial costs incurred in the litigation, the causes of action, obviously are all part and parcel of the ANDA. We would not be able to separate those."

In this case, Apotex similarly confirmed "Apotex's position, as noted, is that the approved ANDAs are the 'interests' within Article 1139(h). Apotex has shown that the ANDA-related activities (contract research, preparation and maintenance of ANDAs, ANDA-related litigation) constitute resources committed to the U.S. territory from which the Marketing Authorizations arose. Article 1139(h) requires no more than this."

The arguments on this point, thus, are essentially the same in both cases, we would submit.

As to the argument that 1139(h) requires no more than committing a resource to the United States, the Apotex I and II Tribunal stated as follows. "None of the items identified (by Apotex) under NAFTA Article 1139(h) amounts to an investment within NAFTA

1256

Chapter 11, and whether considered separately or together, none changes the analysis" under--in this case, under Article 1139(g), property.

Thus, just because Apotex spends money preparing ANDAs and litigating ANDAs in court, the money spent doesn't transform the ANDA application into an investment for purposes of Article 1139(h) or bear on the question of whether an ANDA is property for purposes of Article 1139(g).

Now, based on this conclusion, the U.S. Rejoinder stated that the Apotex I and II Tribunal "rejected the argument advanced here that an ANDA constitutes intangible property for purposes of Article 1139(g), and, hence, separately constitutes a qualifying interest for purposes of Article 1139(h)."

In its Rejoinder on Jurisdiction, Apotex characterized the U.S. argument as follows: "The closest U.S. Rejoinder comes to presenting an argument on this point is its assertion that Apotex I and II rejected that an application constitutes property, 'and, hence, separately constitutes a qualifying interest' for purposes of Article 1139(h)." This is

1257

correct. The United States did point that out.

But then Apotex says, "The U.S. thus suggests for the first time in its Rejoinder, without support or explanation, that 'property' in Article 1139 means the same thing as 'interests.'"

But if I could just return to the previous slide, the U.S. Rejoinder stated that the Apotex I and II Tribunal rejected the argument advanced here, that an ANDA constitutes intangible property for purposes of Article 1139(g), and, hence, separately, a qualifying interest for purposes of Article 1139(h). Apotex's characterization of the United States's arguments, we would submit, is not accurate. The United States nowhere suggests that property in Article 1139(g) means the same as interests in Article 1139 (h).

But in any event, the crucial point is that the Apotex I and II Tribunal rejected the argument advanced here, that ANDAs are property under Article 1139(g) and, for that reason, also qualify as investments under Article 1139(h).

Let me move on to Apotex's second 1139(h)

1258

argument. Apotex argues that its "ANDAs are committed to economic activity in the territory of the United States." Apotex states that "by filing an ANDA, Apotex seeks authorization to market its products in the United States and not anywhere else in the world. It is undisputed that an approved ANDA cannot be used outside the United States. As such, whenever Apotex submits an ANDA, it commits to economic activity in the United States."

Again, this is the very argument that Apotex advanced in Apotex I and II stating, "Apotex cannot export and commercialize anything in the United States without an approved ANDA, and without undertaking the investment and development that goes into that ANDA. An ANDA is, therefore, a uniquely United States investment."

So once again, the Apotex I and II Tribunal considered and rejected this argument, stating, "The Tribunal is unpersuaded that the costs and effort expended in preparing ANDAs either constitutes or evidences an investment in the United States for purposes of NAFTA Chapter 11. This is for a number of

1259

reasons."

One of the reasons stated by the Tribunal is that "An ANDA must be submitted by any manufacturer of generic drugs that seeks to have its products sold in the United States. This is so regardless of whether the manufacturer is investing in or merely exporting to the United States. Consequently, the preparation of the filing, in and of itself, does not establish that a generic drug manufacturer is investing in, rather than exporting products to, the United States."

Ms. Thornton, I think, pointed out that the Grand River Tribunal also noted that, "where a company must meet regulatory requirements to sell its product in the United States, the costs of such compliance themselves are not investments. Rather, those costs are incident to commercial contracts for the sale of goods or services, which fall outside the Article 1139's definition of 'investment.'"

The Apotex I and II Tribunal concluded that "allowing a mere application for regulatory clearance to export goods into the United States to give rise to an 'investment' claim under Chapter 11 would be

09:03:30 inconsistent with the core objectives of NAFTA" Chapter 11. The submission of an ANDA, therefore, does not create an interest under Article 1139(h). Apotex's second argument, thus, fails.

Apotex's third argument on Article 1139(h) is that ANDAs, although prepared in Canada, reflect the commitment of resources in and into the United States. In that regard, Apotex states that "When Apotex develops, files, and maintains an ANDA, it commits capital, intellectual property rights, know-how and other resources in and into the United States."

Apotex cites three examples of these alleged resources: One, funding lawsuits in the United States; two, contributions through a 2005 Services Agreement with Apotex Corp.; and, three, including in its ANDAs know-how, intellectual property, and proprietary information.

Apotex first contends that Apotex Inc. "regularly engages in costly patent litigation before U.S. courts to give value to its ANDAs. The litigation and its attendant expense represent a commitment of capital and resources into the United

09:04:47 States."

Again, this is precisely the argument that Apotex unsuccessfully advanced in the Apotex I and II claims. There, Apotex argued that it incurs "substantial litigation costs" in patent litigation in U.S. courts, which represent a "commitment of money and other resources" in the United States for purposes of Article 1139(h).

The U.S. responded in that case that if a Canadian or Mexican exporter could transform itself into an "investor" with an "investment" in the United States simply by filing a lawsuit to further its cross-border trade, then presumably, every such exporter could bring its trade-related disputes to investment arbitration under the NAFTA. NAFTA Chapter 11, however, expressly defines the investors and investments entitled to protection so as to prohibit such bootstrapping.

The Apotex I and II Tribunal agreed with the United States, stating that Apotex's "engagement of U.S. attorneys and its expenditure on legal fees again neither amount to investments nor change the nature of

09:05:53 Apotex's activity. Each is, again, no more than an incident of the regulatory requirements of the U.S. market and a step Apotex took in order to facilitate its export business.

NAFTA 1139(i) once again applies. The fact that Apotex regularly engages in costly patent litigation in the United States merely facilitates its cross-border trading activities. It does not establish an investment in the United States.

Apotex's second argument in this regard is that Apotex Inc. has committed resources to Apotex Corp. through a 2005 Services Agreement. In its Memorial, Apotex suggested that the 2005 Agreement actually called for Apotex Inc. to pay Apotex Corp. for administrative services. It stated "Apotex-Canada relies on a full-time employee based in Weston, Florida, to act as its agent and liaison with FDA concerning the filing of ANDAs. Apotex-Canada's agent works with a team of six people in carrying out this work. In particular, this team addresses any questions that FDA may have once an ANDA has been filed. Apotex-Canada funds this team's work through a

09:07:12 2005 Services Agreement with Apotex-U.S. By arranging and maintaining such a workforce in the U.S., Apotex-Canada is submitting resources in that territory."

Now, we would submit that this paragraph is not exactly a model of clarity in several respects: "relies on a full-time employee," "works with a team," "arranges a workforce." It is not clear what any of these verbs are actually performing, but what is clear about this paragraph is Apotex's statement that Apotex Inc. "funds" the team's work through a 2005 Services Agreement.

Apotex makes this argument to try to show that the 2005 Services Agreement constitutes a commitment of capital in the U.S. for purposes of Article 1139(h). As the U.S. Counter-Memorial pointed out, this claim was not accurate. The 2005 Agreement, by its terms, does not call for Apotex Inc. to fund any aspect of Apotex Corp.'s work. It calls for the opposite: Apotex Corp. was to pay Apotex Inc. for certain administrative services.

In its Reply, Apotex acknowledged that the

1264

U.S. asserts, correctly, that the 2005 Services Agreement between Apotex-Canada and Apotex-U.S. requires that Apotex make a cash payment to Apotex-Canada for certain administrative support, and not the other way around.

This might have been the end of the story, but Apotex then argued that, However, the Services Agreement reflects a large contribution from Apotex-Canada to Apotex-U.S., including administrative services, accounting and financial, payroll services, information systems, technology services, as well as other services that may be, from time to time, requested by Apotex-U.S. The cash payment only compensates Apotex-Canada for a small portion of the services that Apotex-Canada provides to Apotex-U.S. In other words, Apotex-Canada commits various resources to Apotex-U.S. through the Services Agreement.

This statement directly contradicts the express terms of the Services Agreement itself. Paragraph 4.1 of the Agreement sets out the scope of the services provided to Apotex Corp. by Apotex Inc.

1265

In this case, Apotex is referred to--Apotex Corp. is referred to Corp. "Apotex Inc. shall provide to Apotex Corp. administrative services, information systems and technology services, accounting and financial (including payroll) services, procurement services, human resource services, logistic services including inventory management, quality assurance control services, facility services, engineering services, and such additional services which may be requested by Apotex Corp. from time to time."

1266

CONFIDENTIAL PORTION

MR. SHARPE: Paragraph 3 establishes Apotex Corp.'s agreement to pay Apotex Inc. for all such services. "In consideration of Apotex Inc. providing the services herein for and on behalf of Apotex Corp., Corp shall pay to Apotex Inc. during the term hereof the sum of [redacted] Canadian on a monthly basis for all services rendered by Apotex Inc. to Apotex Corp. pursuant to Paragraph 4."

So, Apotex Corp. thus, pays [redacted] Canadian each month, or [redacted] per year, for all services rendered by Apotex Inc. under the Agreement.

1267

NONCONFIDENTIAL PORTION

MR. SHARPE: Paragraph 11.1 makes clear that the terms of the 2005 Agreement "constitute the entire Agreement between the Parties with no representations, warranties, covenants, agreements or understanding relative thereto except as otherwise set forth herein."

MR. LEGUM: May I just interrupt for a moment.

Going back to the Services Agreement and the specific provision that talked about the payments being made between the two companies, that has been designated as confidential, and in our view, it does reflect confidential business information. Obviously it's too late for anything to be done about the public feed, but I would request that that portion of the transcript be marked as confidential.

MR. SHARPE: Understood. Perhaps, given that this was reflected in the slides, if we hand out something--we're trying to be very mindful of the confidential information and to redact. In this regard, we've been guided by the redactions that

Claimants have made to our submissions. And if I recall correctly, this was not redacted, but I may be corrected.

PRESIDENT VEEDER: I think I just checked. It was a confidential document.

MR. SHARPE: I understand.

PRESIDENT VEEDER: So I think we should take the passage out from the transcript.

MR. SHARPE: Right. I have no objection to that, but I would just reiterate that most of the documents in this Arbitration, fact documents were designated "Confidential" and then it gave the Parties an opportunity to redact certain information from each other's submissions.

The United States, as I recall, has not had to redact anything from our submissions.

PRESIDENT VEEDER: Let's not get into that. There's a double system; the first level, this should have been--and maybe I should have intervened. I apologize. This should have been a closed session. The damage is done, if any damage at all.

Do we need to go back into open session or

closed session again in order to decide that? Or have you finished your references to this document?

MR. SHARPE: I have just one more paragraph. Perhaps without referring to the document at all, I could just suggest that if the Tribunal reviews the entire agreement clause.

PRESIDENT VEEDER: We've done that. We've got it in front of us.

MR. SHARPE: Very good.

Therefore, Apotex's current characterization of the 2005 Services Agreement is, in our view, the exact--is not only contrary to the terms of the Agreement, but it's exact opposite of what is argued outside of this Arbitration.

In the Cephalon case in U.S. court, Apotex stated, "Cephalon notes that Apotex Corp. contracts with Apotex Inc. for administrative services but has not shown that this Agreement is nearer than arm's length in any way."

An arm's-length transaction, by definition, is one that takes place between independent entities with each looking to get the best deal for itself.

The 2005 Services Agreement, we submit, cannot both be an arm's-length agreement and permit Apotex Corp. to pay Apotex Inc. for a small portion of the services that Apotex Corp. receives from Apotex Inc.

Apotex's Rejoinder on jurisdiction further undermines its claims. Apotex first reiterated its argument that "Although the Services Agreement requires Apotex Corp. to make a cash payment to Apotex Inc."--

Sorry. Is this portion designated confidential in our submission?

MR. LEGUM: I'm sorry. I was taking notes. I need to catch up as to what we're looking at now.

PRESIDENT VEEDER: We're looking at the Services Agreement. It's a confidential document.

MR. SHARPE: I'm quoting from the submission. I don't recall that this was redacted.

MR. LEGUM: It's just the specific numbers that, I think, pose an issue.

MR. SHARPE: Yes, I have it in the public version, so this was not redacted. If I recall correctly, the previous was a public version as well.

Well, we'll check on that.

If I may quote again, "Although the Services Agreement shows Apotex Corp. to make a cash payment to Apotex Inc. for certain administrative support, this Agreement reflects a larger contribution from Apotex Inc. to Apotex Corp."

Apotex then states that "The U.S. attempts to rebut this fact by focusing on the text of specific provisions of this Services Agreement taken in isolation, rather than the record on how the Agreement was implemented in practice. However, in doing so, the U.S. ignores the spirit of the Agreement and the way operations are carried out in a vertically integrated group of companies."

Apotex thus asks this Tribunal to ignore the text, the plain terms of the Contract, and rely instead on its spirit. This Tribunal, we submit, should decline to do so. I note that the Claimants in Grand River similarly invited the Tribunal to find an investment under Article 1139 by looking at the undocumented manner customary among indigenous peoples rather than the relevant text. The Grand River

09:15:34 Tribunal declined to do so, concluding that "the assertions of undocumented understandings customary among indigenous peoples are too vague and lacking in evidentiary support to make out an enterprise from the record."

Here, too, there is no evidentiary support showing that the 2005 Services Agreement operated as anything other than an arm's length agreement. There is no board resolution, for instance, authorizing Apotex Inc. to provide free services to Apotex Corp., and we would assume that Apotex Inc. is not providing free services to Apotex Corp. to the detriment of Apotex Inc.'s minority shareholders, its employees. These employees, of course, have no share in Apotex Corp. and thus presumably would not benefit from Apotex Inc. providing free services to Apotex Corp. Although Apotex represented in U.S. court that Corp and Inc. have studiously observed all corporate formalities, Apotex has declined to produce any evidence that it abandoned these formalities in this regard.

Instead, Apotex merely states that "the U.S.

09:16:39 offers no response to Apotex's observation that the mere fact that consideration is paid for a contribution of capital or resources in no way negates the existence of that contribution, as shown by the examples of share issuance for capital contributions for a Shareholder loan for cash contributions noted in Apotex's reply."

Apotex appears to suggest here that the 2005 Agreement puts Apotex Inc. in the position of a Shareholder or a lender who receives an equity or debt interest for its contribution of services. But the United States did respond to this argument. As stated in the U.S. Rejoinder, "Apotex's own testimony forecloses any suggestion that Apotex Inc. has an equity or debt interest in Apotex Corp."

Its Vice President of Finance testified that "Apotex Inc. has no direct or equity stake in Apotex Corp; Apotex Corp. has never borrowed any funds from Apotex Inc.; Apotex Inc. has never provided any financing to Apotex Corp."

Apotex's argument that the 2005 Services Agreement reflects a kind of contribution to

09:17:49 Apotex Corp. for purposes of Article 1139 is, we submit, demonstrably false. To the contrary, the Agreement makes clear that, on its terms, it is an ordinary arm's-length Services Agreement between two separate and distinct companies. It is, therefore, expressly excluded by Article 1139(i) which, to remind, states "Investment does not mean: (i) claims to money that arise solely from commercial contracts for the sale of goods or services by a national or enterprise in the territory of a Party to an enterprise in the territory of another Party."

The 2005 Services Agreement is nothing more than a commercial contract for the provision of services. It has nothing to do with any U.S. investment, and Apotex's arguments to the contrary are not supported, and we think should have been abandoned months ago when the U.S. Counter-Memorial clarified the terms of that Agreement.

Nor is there any basis to conclude that Apotex Inc. can claim to be an investor derivatively through Apotex Holdings in this regard. Any contributions of resources made by Holdings go to the

09:19:01 question of whether or not Apotex Holdings, not Apotex Inc., is an investor with an investment in the United States.

Apotex's final argument on Article 1139(h) is that the "interests arising from the commitment of capital or other resources in the host State should be read to mean 'within or without the host State,' so long as the capital or other resources are committed or devoted to economic activity in the territory of the host State."

This is an extraordinary argument that no NAFTA Tribunal has ever accepted. As the U.S. Counter-Memorial stated, "There is no basis to conclude that the NAFTA Parties intended the word 'in' to mean 'within or without.' Apotex's reading of Article 1139(h) contradicts the ordinary meaning of Article 1139(h) read in context in the light of NAFTA's object and purpose; (2) the NAFTA Party's shared understanding of Article 1139(h); and, (3), the unanimous views of other NAFTA Chapter 11 Tribunals."

I would direct the Tribunal to Paragraphs 245-263 of the Counter-Memorial for this discussion.

We continue to find Apotex's Argument perplexing in this regard, given the plain terms of Article 1139 which define investment as including "interests arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory." This provision makes clear that the investor's interests must arise from the commitment of capital of other resources in the territory of a Party to economic activity in such territory.

There is no dispute that the French text provides the same formulation as the English text. Apotex asserts that the French text has not been authenticated. NAFTA Article 2206 states that the English, French, and Spanish text of this Agreement are equally authentic. All three texts have been published by the NAFTA Secretariat, and two of the Parties have cited the French language version of Article 1139(h) in this very arbitration, the United States and Mexico. There is no reason for the Tribunal to go beyond those terms in this very case.

Our Treaty Office has also confirmed that the

Agreement was signed in triplicate and has an authenticated French language text.

Apotex has produced no Authority to suggest that the Tribunal should read the Spanish language text differently from the English and French texts, introducing an ambiguity that would not otherwise exist. This is especially impermissible given that Claimants' interpretation, we submit, is contrary to the object and purpose of the Agreement, which to protect cross-border investment, as Ms. Grosh mentioned, not investments made in the territory of the Home state.

Apotex is not making a pre-establishment claim in this Arbitration. It does not claim that it was seeking to make an investment in the United States. It claims that it made an investment, it had investments. An investment requires, under the plain terms of Article 1139(h) a commitment of resources in the territory of the host State.

In any event, even if the Spanish text might be read differently from the English and French texts, Mexico has urged this Tribunal not to give Article

1139(h) a meaning that is different from the ordinary meaning derived from the English and French texts. Mexico's non-disputing Party submission in this case states that, "Mexico fully concurs with the U.S. submissions stated in its Counter-Memorial, Paragraphs 245-263, with respect to the interpretation of Article 1139(h). In Mexico's submission, the Tribunal should take into account Article 1101(1) as part of the context to correctly interpret Article 1139(h)."

Mexico noted that Article 1101(1) serves as the gateway leading to dispute resolution provisions under Chapter 11 and provides clear guidance that only investments of an investor of a Party located in the territory of another Party fall within the scope and coverage of the Chapter 11.

Mexico then stated, "Therefore, each and every kind of investments listed in Article 1139 must comply with this territorial requirement, and applying this component is part of the context to interpret Article 1139(h), it is clear that it requires a commitment of capital or other resources of an investor of a Party in the territory of another

Party."

Mexico clearly rejects Apotex's argument that an investor of a Party may obtain an investment from the commitment of capital or other resources made outside the territory merely because those resources are devoted to the territory through cross-border trade activity.

As to any discrepancy between the Spanish text, on the one hand, and the French and English texts on the other, Mexico stated "Applying Article 33(4) of the Vienna Convention on the Law of Treaties, even if a comparison of the three versions of NAFTA (English, French, and Spanish) might disclose a difference of meaning in NAFTA Article 1139(h), it can be seen that the text of the English and French versions are, on their face, consistent with Article 1101(1) and, thus, any perceived discrepancy with the Spanish text is best reconciled by upholding the territoriality requirement."

Indeed, according to Mexico, "An interpretation of Article 1139(h) that does not take into the territoriality requirement of Article 1101(1)

as part of the context would render the clear scope and coverage limitation meaningless."

Canada also shares this view. In S.D. Myers, for instance, Canada objected to the claim that, for purposes of Article 1139(h), the Claimant had "committed capital by way of operating loan financing and invested capital by way of common shares in the Canadian affiliate." Canada argued that the Claimant had failed to prove that the alleged commitment of capital was more than some sort of accounting entry, as opposed to a real investment in Canada."

Canada further observed that "there is no evidence that the funds were actually disbursed in Canada."

Thus, none of the NAFTA Parties accepts Apotex's Argument that Chapter 11 protects interests arising from the commitment of capital before they are committed to the host State. Indeed, the suggestion that NAFTA Parties intended to protect, as investments in their territory, money committed outside of their territory is fundamentally at odds with NAFTA Parties' shared understanding of its meaning.

Article 31(3) of the Vienna Convention states, as a general rule of Treaty interpretation, that the interpreter is to take into account, together with context, "any subsequent Agreement between the Parties regarding the interpretation of the Treaty or the application of its provisions; any subsequent practice in the application of the Treaty which establishes the Agreement of the Parties regarding its interpretation."

Here, the Tribunal must take into account the NAFTA Parties' subsequent agreement or subsequent practice. Indeed, the Tribunal should consider the common, concordant, and consistent views of NAFTA Parties in this regard, the authentic interpretation the NAFTA binding on this Tribunal.

Thank you, Mr. President and Members of the Tribunal, that concludes my remarks on 1139(h).

If there are no further questions, we can proceed.

PRESIDENT VEEDER: Thank you. Thank you very much. We have no questions at this stage.

It's now 9:30. Would this be a good time to

take a short break? Let's take a 10-minute break and come back at 20 to 10:00.

(Brief recess.)

PRESIDENT VEEDER: Let's resume.

MR. SHARPE: Thank you, Mr. President, Members of the Tribunal. I will now address Apotex's failure to establish that the challenged measure "relates to" Apotex or its alleged investments as required by NAFTA Article 1101(1).

I plan to address three points. First, I'll briefly address the Parties' agreement on the requirement to show a legally significant connection between the challenged measure and investor and investment.

Second, I'll briefly address Apotex's proposed test for satisfying that standard.

Third, I'll address the relevant measure in this arbitration--measures demonstrating how each measure, legally, does or does not relate to each investor and investment. In particular, I'll show how the Import Alert did not relate to Apotex Inc.'s alleged investment, its ANDAs, or to the U.S.

enterprise Apotex Corp.

Let me first begin with the Parties' Agreement on Article 1101(1). As Ms. Grosh discussed, Article 1101(1) is the investment chapter's scope and coverage provision. And as the Methanex Tribunal confirmed, it is the gateway to dispute resolution under Chapter 11.

As we've discussed, Article 1101(1) states, in part: This chapter applies to measures adopted or maintained by a Party relating to, investors of another Party, and investments of investors of another Party in the territory of the Party.

When the issue first arose in Methanex, United States observed that: In the context of Article 1101(1), the phrase "relating to" requires a legally significant connection between the disputed measure and the investor. Were it otherwise, the United States explained, untold numbers of local, state, and federal measures that merely have an incidental impact on an investor or investment might be treated, quite wrongly, as "relating to" that investor or investment.

1284

09:42:04 Canada shares this interpretation. In a non-disputing Party submission in Methanex, Canada stated that it agreed with the United States that the term "relating to" requires a significant connection between the measure at issue and the essential nature of the investment. And Mexico also shares this interpretation. In a non-disputing Party submission in Methanex, Mexico stated that: The test adopted for the purposes of Article 1101(1) must reflect the NAFTA drafters' intent to require a more direct nexus between the measure and the investor or its investment than mere effect, as evidenced by the text's considered use of "relating to." The Methanex Tribunal confirmed the NAFTA Parties' shared interpretation, finding that the phrase "relating to" in Article 1101(1) of the NAFTA requires--signifies something more than the mere effect of a measure on an investor or an investment, that it requires a legally significant connection between them, as the USA contends. The Methanex Tribunal did not pronounce a general rule on when a measure might have a legally significant connection to an investor or an

1285

09:43:17 investment, leaving it to Claimants in future cases to establish the legally significant connection on a case-by-case basis.

Here, Apotex accepts that "The 'relating to' language in Article 1101(1) requires a legally significant connection between measure and investment/investor, as held by the Methanex Tribunal."

The question before the Tribunal, therefore, is whether Apotex has established that the sole challenged measure in this case, the Import Alert, had a legally significant connection to each alleged investor and investment.

To answer the question, Apotex invites the Tribunal to apply the following test. "If a Measure breaches a substantive provision of Chapter 11, the connection between the Measure and the investor/investment necessarily is 'legally significant.'" Thus, according to Apotex, a Claimant can pass through NAFTA's jurisdictional gateway by proving its Merits claims. This test, we submit, is entirely circular, and even Apotex acknowledge that

1286

09:44:32 its argument begs the question of what gateway function Article 1101(1) then has.

Apotex's support for its argument is the Methanex Award. According to Apotex's Reply at Paragraph 103, "The Methanex Tribunal recognized that the legally significant connection under Article 1101(1) must be informed by the substantive provisions of Chapter 11." This is not correct. The Methanex Tribunal concluded, as Apotex noted earlier this week, that a breach of a substantive provision of NAFTA "could conceivably provide evidence relevant to a determination of whether the relation required by Article 1101(1) exists in this case."

Thus, establishing a breach of Chapter 11 says nothing, by itself, about the relationship between the breach and any particular investor or investment. That is particularly true in a case like this one, where Claimants have made claims on their own behalf, under Article 1116, as well as on behalf of an enterprise, under Article 1117. One still has to look at how a particular breach relates to a particular investor or investment.

1287

09:45:48 Here, there are two alleged investors: Apotex Holdings and Apotex Inc.; and two alleged investments, Apotex Inc.'s ANDAs and Apotex Corp.

To remind, Apotex Holdings indirectly owns Apotex Inc. and Apotex Corp., but Apotex Inc. does not own or control Apotex Corp. These companies are, as Apotex has repeatedly stressed in U.S. court proceedings, entirely separate and independent companies.

The three Measures implicated in this case are one, FDA's determination that the Etobicoke and Signet facilities were not cGMP compliant--that's Measure One; Two, the Import Alert; and Measure Three, the detention of seven drug shipments from Etobicoke and Signet. There are two key reasons for keeping these Measures straight. First, each Measure has a different legal relationship with the alleged investors and investments in this arbitration. And second, Apotex only challenges one of the three Measures, the Import Alert, or Measure Two.

As Mr. Bigge discussed yesterday, there's a reason why Apotex has not challenged Measure One.

When FDA determined that Etobicoke and Signet were not cGMP compliant, Apotex did not dispute that determination. In fact, Apotex accepted FDA's determination contemporaneously and pledged comprehensive corrective action to remedy the cGMP violations. Apotex has gone so far as to dismiss its cGMP violations as "legally irrelevant" to this arbitration in Paragraph 41 of its Reply. That is, we submit, not true, which I'll discuss shortly.

There's also a reason why Apotex has not challenged Measure Three. Apotex was given notice and an opportunity to present evidence at detention hearings, but it declined to appear and challenge the detentions. That's not disputed in this arbitration. Instead, Apotex has challenged only Measure Two, the Import Alert. That is the only Measure that Apotex has challenges in this arbitration is as a nonbinding internal FDA memorandum.

Let me start with Measure One: FDA's determination that the Etobicoke and Signet facilities were not cGMP compliant. Apotex suggests that FDA's determination was not a Measure separate from the

Import Alert. It argues that by identifying three distinct Measures, the United States disaggregates a decision from the reasons that support it and the means to enforce it." That is, Apotex suggests that the Import Alert is the decision; the cGMP violations are the reasons supporting the decision; and detentions at the border are the means to enforce it.

As Mr. Bigge and Mr. Vodra have discussed, this is not correct as a matter of law. FDA's determination that a facility is not cGMP compliant is a separate Measure with distinct legal consequences. There are at least two legal consequences to Measure One that are relevant to this case.

First, under U.S. law, FDA can withhold approval of an ANDA because of cGMP violations. The U.S. Counter-Memorial observes: The Code of Federal Regulations authorizes FDA to "refuse to approve an abbreviated application for a new drug under Section 505(j) of the Act" for a number of stated reasons, including if; one, the methods used in or the facilities and controls used for, the manufacture, process, and packing of the drug product are

inadequate to ensure and preserve its identity, strength, quality, and purity."

Thus, FDA may withhold approval of an ANDA solely because a facility does not adequately comply with cGMP. FDA does not need to take further action before doing so. Nor does FDA need to place the facility on Import Alert before withholding approval of an ANDA. There is no reference to Import Alerts in this provision because Import Alerts have nothing to do with approval or nonapproval of ANDAs.

This is evident on the face of the Etobicoke Warning Letter, which FDA sent Apotex in June of 2009. The letter states that the 2008 Etobicoke inspection: "revealed significant deviations from U.S. Current Good Manufacturing Practice, (cGMP regulations), Title 21, Code of Federal Regulations, Parts 210 and 211, in the manufacture of non-sterile oral solid dosage drug products."

The letter then highlighted one of the consequence of Apotex's cGMP violations: "Until all corrections have been completed and FDA has confirmed corrections of the deficiencies and your firm's

compliance with cGMPs, this office may recommend withholding approval of any new applications or supplementals listing your firm as a drug product manufacturer."

Obviously, this letter from June 2009 had nothing to do with the Import Alert because FDA had not added Etobicoke to the Import Alert until the end of August of that year. Later, when FDA actually declined to approve an ANDA for a drug that was to be manufactured at Etobicoke, the Agency nowhere mentioned the Import Alert. Rather, FDA informed Apotex in an August 2010 letter: "We cannot approve this ANDA application in the present form because the Center for Drug Evaluation and Research, CDER, is unable to find that the methods used in, and the facilities and controls used for, the manufacture, processing, packaging, or holding of this drug at issue...by Apotex Inc. in Etobicoke...comply with Current Good Manufacturing (cGMP) regulations.

FDA added, Until such time that you can demonstrate to the Agency that the problems have been corrected and the Agency's concerns are otherwise

1292

09:52:11 satisfied, your application cannot be approved. Again, this letter nowhere mentions the Import Alert as approval or nonapproval of an ANDA. It has nothing to do with an Import Alert.

As the U.S. Counter-Memorial observed at Paragraph 275: The bar that prevented Apotex's approval of Apotex's unapproved ANDAs was not the Import Alert but Apotex's own cGMP failures. In other words, the legal impediment was Measure One, not Measure Two.

After the U.S. filed its Counter-Memorial--

MR. LEGUM: If I can just interrupt for a moment. I would note that Slide 9 contains references to products, specific products that are not redacted.

MR. SHARPE: Is this not the Warning Letter that was posted to the Web site?

MR. LEGUM: I don't believe it's a Warning Letter, no.

MR. SHARPE: Well, we can move off this slide.

After the United States filed its Counter-Memorial, Apotex dropped its claim that the

1293

09:53:15 unapproved ANDAs constitute investments. As a result, the Tribunal does not need to address this particular issue, but I highlight the point because it clearly shows one of the principal legal effects of Measure One; that is, FDA's determination that Etobicoke and Signet were not cGMP compliant. It also shows the legal irrelevance of Measure Two, the Import Alert, to the question of Apotex ANDA approval. To put it in Chapter 11 terms, the Import Alert had no legally significant connection to Apotex's unapproved ANDAs.

So let me turn to an issue that's still pending, did the Import Alert have a legally significant connection to Apotex's finally approved ANDAs? Apotex argues that it did. It claims that the Import Alert "rendered the ANDAs useless" and "destroyed the economic value of the ANDAs because the products authorized to be marketed by the ANDAs could not be marketed at all while the Import Alert remained in effect."

Again, this assertion is incorrect. All of Apotex's approved ANDAs remained approved during the period of the Import Alert. Apotex, thus, could have

1294

09:54:25 transferred them to another Apotex facility or to a third-party facility or it could have sold them. Had Apotex transferred the ANDAs, it could have continued exporting the ANDA products to the United States, notwithstanding the cGMP violations at Etobicoke and Signet and notwithstanding the Import Alert. What Apotex could not do was export to the United States adulterated drugs made in non-cGMP compliant facilities as those drugs were legally deemed to be adulterated.

Apotex does not dispute that it could have sold or transferred its ANDAs. Instead, Apotex argues that it had decided in November 2009 that transferring its ANDAs would have been impractical. Apotex claims that it did not know that it would take nearly two years to bring its facilities back into compliance with U.S. law. Apotex, thus, made a business calculation about its ability to remedy its cGMP violations. But Apotex has not proven its assertion that the Import Alert had any effect on the utilization of its ANDAs as investments in the United States. In fact, outside of this arbitration, Apotex

1295

09:55:37 represented to U.S. court that there were no impediments at all to the continued use of its ANDAs, whether legal, practical, or otherwise.

In patent litigation over the drug modafinil, another drug company had tried to block Apotex from obtaining a period of market exclusivity for that drug. The company argued that the cGMP violation and Import Alert constituted a barrier to FDA approval of the modafinil ANDA. Apotex rejected the argument representing to the Court in April 2010 that: Apotex has plants throughout the world. The Import Alert and related Warning Letters apply to only two Apotex facilities. While Apotex's ANDA from modafinil identifies one of two Ontario facilities as the manufacturing site, Apotex can file appropriate technology transfer documents with the FDA that would allow manufacture at another FDA-approved Apotex manufacturing site.

See, 21 CFR 314.70(a). Apotex continues to manufacture product at such sites and to import such product into the United States because those facilities are not subject to the Import Alert. There

are two crucial concessions in this statement.

First, Apotex rejects any suggestion that the Import Alert relates to Apotex's ANDA for modafinil. To the contrary, Apotex states that the Import Alert concerns two Apotex pharmaceutical facilities in Canada; that is, Apotex contradicts its argument here that the Import Alert relates to the ANDA itself.

Second, Apotex acknowledges that it could have continued using the modafinil ANDA at one of its other plants throughout the world. Apotex does not say that it would have been impractical for Apotex to transfer the ANDA to another facility, let alone legally impossible. It makes no qualifications of any kind.

This Tribunal, we submit, should not permit such opportunistic pleading. Good faith requires that a Party not blow hot and cold, affirming at one time and denying at another. This is a general principle of law long recognized by international courts and tribunals.

Mr. President, Members of the Tribunal, the evidence shows that the sole challenged Measure in

this case does not relate to the only investments claimed by Apotex Inc., its abbreviated New Drug Applications. As such, even if this Tribunal were to find that Apotex Inc. were an investor under Article 1116 and that its drug applications constituted investments under Article 1139, the Tribunal still would lack jurisdiction over any claims by Apotex Inc. Apotex has failed to prove a legally significant connection between the Import Alert and its ANDAs. The claims of Apotex Inc., thus, fall outside of the Chapter 11's scope and coverage, as set forth in Article 1101(1).

Let me now turn to Apotex's failure to establish that the Import Alert related to Apotex Holdings or to its U.S. investment, Apotex Corp.

Apotex alleges that the Import Alert interrupted sales from Apotex Inc. to Apotex Corp. and thereby made it legally impossible for those transactions to be carried out. This argument we submit, fails in three respects.

First, the evidence indicates that Apotex Inc.'s sales to Apotex Corp. occur entirely in Canada,

and, thus, no U.S. Government Measure interrupted those sales.

Second, to the extent that Apotex complains that Apotex Corp. could not import drugs from Etobicoke and Signet, the legal impediment was not the Import Alert--Measure Two--but Apotex's cGMP violations, Measure One.

Third, even if the Import Alert had been the legal impediment to importation of drugs from Etobicoke and Signet, the connection between the Measure and Apotex Corp. is simply too remote to be legally significant.

Let me start with the location of Apotex's drug sales. It is not easy to suss out from Apotex's pleadings where Apotex Corp. purchases drugs from Apotex Inc. Each pleading offers a different but somewhat cryptic statement. The Request for Arbitration, for example, contends that the Import Alert prevented Apotex Corp. from receiving for sale in the U.S. any product manufactured at the Etobicoke and Signet facilities. Apotex--

PRESIDENT VEEDER: Do you have reference to

the paragraph?

MR. SHARPE: Paragraph 38 of the Request for Arbitration.

Apotex declined to produce any relevant evidence to clarify this question.

During bifurcation proceedings, Apotex admitted that Apotex Corp. assumed the risk of loss when Apotex Inc. handed over its products to a carrier at the facilities of Etobicoke and Signet. Now, it's possible that Inc. continued to own its products even after it handed over the products to Apotex Corp. and after Apotex Corp. assumed the risk, but there is no evidence to that effect. In fact, all the evidence is to the contrary. Apotex has stated categorically that Apotex Inc. does not directly sell any products of any kind in the United States. It has said because Apotex Inc. does not directly sell any products in the U.S., it must rely on the products being sold by others, such as Apotex Corp. And Apotex Inc. has put nothing into the stream of commerce in the United States.

Apotex nonetheless represented to this Tribunal in its Rejoinder on Bifurcation, Note 53:

1300

10:01:46 Contrary to the U.S. contention, Apotex has never suggested that title passed to Apotex Corp on delivery of goods to the carrier.

This statement, we submit, is not correct. In the Sanofi patent litigation in Canadian courts, Apotex suggested a title does pass to Apotex Corp. on delivery of the goods in Ontario. In that case, Apotex had sought to take advantage of the shorter limitations period under Ontario law by arguing that the cause of action arose entirely in the province of Ontario. Apotex thus stated: Any manufacture, sale, or use of clopidogrel or any clopidogrel-containing product by Apotex Inc. or Apotex Pharmachem took place in and only in Ontario. Any manufacture, sale, or use of clopidogrel or any clopidogrel-containing product by Apotex Inc. or Apotex Pharmachem outside of Ontario, which is denied, does not constitute infringement of the Sanofi-Aventis patent.

Specifically, with respect to the U.S., the Apotex Defendants state that at all times prior to June 9, 2007, the Plaintiffs knew that the Apo-clopidogrel product was manufactured, sold, and

1301

10:03:09 used, if at all, by Apotex Inc. solely in Ontario, Canada.

The federal court in Ontario highlighted Apotex's clear statement to the effect that any sales of the product by Apotex occurred in Ontario and in Ontario only. The Court found it inescapable on the pleadings that any sales by Apotex Inc. of product eventually sold in the U.S. were made in Ontario, either directly to Apotex Corp. or to an intermediary, and that any export was, therefore, made by Apotex Corp. or to this intermediary. Paragraph 27 of that document. Apotex's pleading, the Court concluded, negates and denies any export by Apotex Inc.

And yet when Apotex argued against bifurcation of these proceedings, it represented to the Tribunal that: The Import Alert interrupted the transactions on which Apotex-U.S. depended for 80 percent of its sales. It added: The Import Alert made it legally impossible for these transactions to be carried out. To use the alternative expression posited by the U.S, the Import Alert was a legal

1302

10:04:23 impediment to the conduct of these transactions. The Import Alert applied equally to both Parties to the transactions.

Now, in light of Apotex's statement in the Canadian and U.S. court proceedings that any and all sales between Apotex Inc. and Apotex Corp. occur in and only in Ontario and that Apotex Inc. does not sell any products of any kind in the United States, we fail to see how any U.S. Government Measure could have interrupted those transactions.

In Apotex's Rejoinder on Jurisdiction, it argues that the context of the Canadian court case is different from this case, as the Canadian case involved a statute of limitations and this case involves jurisdiction under the NAFTA. That is true, of course, but irrelevant. The question is simply whether Apotex Inc. sells its drugs in the United States or in Canada and, thus, whether any U.S. Government Measure interrupted those transactions, as Apotex has claimed repeatedly in this arbitration. As Apotex's statements to the U.S. and Canadian courts show, the answer is clear. The sales occurred in

1303

10:05:35 Canada; no U.S. Government Measure could have interrupted those transactions. This Tribunal, we submit, cannot permit Apotex to argue one thing when it suits its litigation interests and the opposite in these legal proceedings.

Apotex's admission in U.S. and Canadian court proceedings undercut Apotex's heavy reliance on the Cargill case. Apotex has acknowledged that, in Cargill, the Tribunal addressed an import permit requirement that prevented sales of goods between the U.S. parent company and its subsidiary/investment in Mexico.

Apotex's quoted the Cargill Tribunal's statement that the import permit requirement "constituted a legal impediment to carrying on the business of Cargill de Mexico."

Note the three obvious differences between this case and Cargill. First, Cargill owned and controlled its Mexican subsidiary, Cargill de Mexico. Apotex Inc., by contrast, does not own or control Apotex Corp. That is undisputed.

Second, Mexico imposed the permit requirement

directly on Cargill de Mexico in Mexico; that is, the Measure was imposed directly on the investment in the host State. Here, by contrast, the Import Alert was not directed at, and no way applied to, the investor's investment or alleged investment in the host State. It was directed and applied to drugs made at two of Apotex Inc.'s Canada pharmaceutical facilities.

Third, Mexico's import permit constituted a legal impediment to Cargill de Mexico's business. Cargill's investment in that case, Cargill de Mexico, could no longer operate in Mexico without obtaining a permit that the Government declined to grant. Here, by contrast, the Import Alert did not interrupt any sales from Apotex Inc. to Apotex Corp. and did not affect Apotex Corp.'s legal capacity to operate in the United States in any way. Apotex Corp. simply lost the opportunity to sell in the United States supplies from one supplier because those supplies were deemed to be adulterated and could not lawfully be sold in the United States.

Let me turn to my second point. To the extent that Apotex alleges that the Import Alert

related to Apotex Corp. because it prevented Apotex Corp. from importing drugs into the United States for commercial sale, then Apotex still is incorrect. The Import Alert was not the underlying reason that Apotex Corp. or any other company could not import drugs into the United States from Etobicoke and Signet. Apotex itself acknowledges this in its pleadings. It has said: Apotex recognizes that U.S. law grants FDA the authority to refuse admission of goods offered for import if they appear adulterated. Apotex recognizes that: Under U.S. law, a drug is considered adulterated if the methods or facilities used to produce it do not conform to cGMP so as to ensure the safety, identity, strength, quality, and purity of the drug.

And Apotex does not challenge FDA's determinations that Apotex Inc.'s Etobicoke and Signet facilities did not conform to cGMP, dismissing FDA's determinations as legally irrelevant to this arbitration. Apotex, thus, necessarily accepts FDA's authority to have detained without physical examination, and refused to admit, drugs from

Etobicoke and Signet. That is, Apotex does not challenge Measure One.

It argues that Measure One did not have any legal consequences. As I addressed earlier, one legal consequence of Measure One is that FDA could lawfully decline to approve an ANDA application because of cGMP violations. The FDA highlighted that fact in the Etobicoke Warning Letter, but the letter also highlighted a second legal consequence of FDA's cGMP violations. It said: CGMP deviations at Etobicoke cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food and Drug Cosmetic Act. Section 501(a)(2)(B) of the Act states that drugs are adulterated when they are not manufactured, processed, packed, and held according to Current Good Manufacturing Practices. Failure to comply with cGMP constitutes a failure to comply with the requirements of the Act.

FDA warned Apotex of the legal consequences of Apotex's cGMP violations. It said: Failure to correct these violations may result in FDA denying entry of articles manufactured at Apotex Inc.

Etobicoke, Canada, into the U.S. The articles could be subject to refusal of admission pursuant to Section 801(a)(3) of the Act...in that, the methods and controls used in their manufacture do not appear to conform to Current Good Manufacturing Practice within the meaning of Section 501(a)(2)(B) of the Act.

Again, FDA clearly warned Apotex that, because of Apotex's cGMP violations, FDA had authority to detain without physical examination and refuse to admit into the United States drugs from Etobicoke and Signet under Section 801(a)(3) of the Act. This letter was drafted months before issuance of the Import Alert. It nowhere mentions a possible Import Alert as a Measure to enforce this determination.

To the contrary because Apotex's facilities were found non-cGMP compliant, its drugs were deemed to be adulterated, and as such, its products could be detained without physical examination and refused admission to the United States, regardless of whether those facilities were placed on the Import Alert.

Apotex's own evidence shows the effect of the Measure on its business operations in the United

States. Here's a letter from the U.S. Department of Veterans Affairs invoking its right to terminate purchases from Etobicoke. As you can see, the letter is dated July, 22, 2009, more than a month before the issuance of the Import Alert. What's more, the legal grounds stated for termination are the cGMP violations themselves.

This letter is in reference to Apotex Corporation's Federal Supply Schedule Contract: Due to FDA Current Good Manufacturing Practice deficiencies that were revealed in the FDA Warning Letter dated June 25, 2009, for Apotex's manufacturing facilities located at Etobicoke I am invoking the Government's rights set forth in Contract Clause AS213, Paragraphs IV and V. Under these clauses, the Government may reject and return any products that were manufactured during a period of cGMP deficiencies and shipped without written authorization from the Contracting officer to eligible FSS users.

It adds: Please be mindful that my determination to invoke Paragraphs IV and V is based solely on the Warning Letter that was issued by the

FDA. The rights at issue here concern only the cGMP violations as reflected in the Warning Letter. The letter had nothing to do with the Import Alert, which had not even been issued when the letter from the Department of Veterans Affairs was sent.

So, what is the purpose of an Import Alert if the drugs already are deemed to be adulterated with all of the legal consequences that flow from that? As Mr. Bigge discussed yesterday, the purpose of an Import Alert is to identify and disseminate import information, problems, violative trends, et cetera, for providing an effective import coverage program. Import Alerts allow DIOP to disseminate critical information throughout the field to try to prevent the importation of drugs that appear to violate the FD&C Act. In short, the Import Alert provides the factual information that district offices may need to exercise their authority to detain products without physical examination. In fact, outside of this arbitration, Apotex itself has characterized the Import Alert as a "Temporary Import Advisory."

This informational purpose can be seen from

the text of the Import Alert itself. Here on the screen is a copy of the Import Alert for this case. It's in the Core Bundle at Tab 33. The revised date is August 17, 2007, and this is the version from August 28, 2009. You can see from the annex that this is a relevant alert which lists the two Apotex facilities: Apotex Inc. at Etobicoke and Apotex Inc. at Signet. Now, returning to the first page, it states: "Type of Alert: Detention Without Physical Examination. Problem: Failure to meet drug GMPs. Charge: The Article is subject to refusal of admission pursuant to Section 801(a)(3) in that the methods and controls used in its manufacture and control of pharmaceutical products do not appear to conform to Current Good Manufacturing Practices within the meaning of the Section 501(a)(2)(B). Recommending Office: Center for Drug Evaluation and Research, or CDER. Guidance: Districts may detain the specified pharmaceutical products from the firms identified in the attachment to this alert."

Now, the version of the Import Alert from September 27, which Apotex has submitted, has this

additional language in bold text. "Note: This Import Alert represents the Agency's current guidance to FDA field personnel regarding the manufacturers and/or products at issue. It does not create or confer any rights for any person and does not operate to bind the FDA or the public."

This, Members of the Tribunal, is the sole challenged Measure in this Arbitration, and this is what Apotex claims gave a legally significant connection to Apotex Corp.

Now, Apotex does not cite the Import Alert as establishing the legally significant connection. Instead, it cites to a September 2, 2009, Notice of FDA action. That is, Apotex cites FDA documents concerning the detention of Apotex's drugs, or Measure Three.

As you can see at the top, this was issued by FDA's district office in Detroit. The filer is Affiliated Customs Brokers. The Importer of Record is Apotex Inc. The consignee is Apotex Corp. It states "Hold Designated" for various drugs made by Apotex Inc. with the notation "pending FDA review." And as

you can see it's designated at the top "Notice Number 1."

As we discussed in our Counter-Memorial, the purpose of the initial notice is simply to inform the owner, consignee, and customs broker that the listed products are being held and to provide contact information for an agency investigator. FDA, thus, sent the form to all three entities, just as FDA would have sent it to any other consignees that received drugs from Apotex Inc. directly from Canada. Mr. Fahner mentioned three additional consignees in Paragraph 33 of his Second Statement. Each of them, as consignees, would have received a Notice of FDA action if drug shipments to them had been detained.

Here, FDA sent Apotex Inc. and Apotex Corp. Notice Number 2, two days after the Agency sent the first notice. The second notice states "Hold designated" That's the same. The "summary of current status of the individual lines" is "detained." And at this stage, drugs have been detained but not refused admission.

Turning to the second page, the notice

explains that the drugs have been detained because they appear to be adulterated for cGMP violations. It says "Detention Without Examination. The following products are subject to refusal pursuant to the Federal Food, Drug, and Cosmetic Act, Public Health Service Act or other related acts in that they appear to be adulterated, misbranded, or otherwise in violation as indicated below."

For various drugs, the notice states: FD&CA Section 501(a)(2)(B), 801(a)(3); Adulteration." It appears that the methods used in, or the facilities or controls used for, manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with good manufacturing practices. And at the bottom here's the key language Mr. Bigge highlighted yesterday: You have the right to provide oral or written testimony to the Food and Drug Administration regarding the admissibility of the articles or the manner in which the articles can be brought into compliance. This testimony must be provided to FDA on or before the dates shown above."

Let me turn to Notice Number Three, a week

later. It still says "Hold designated" for various drugs. But if you look at Page 2, it says "Lines released after detention, cortisteroid." The reason this drug product was released is because the drug was made at Richmond Hill, not at Etobicoke or Signet; that is, the drug did not appear to be adulterated because it was not manufactured at a non-cGMP compliant facility. As such, it was released into the United States once the correct information had been obtained.

And finally, let's look at Notice Number Four from September 28, 2009. It states under current status "Refuse." Turning to Page 2 it says, "Refusal of admission. Examination of the following products have been made and you have been afforded an opportunity to respond to a Notice of Detention. Because it appears that the products are not in compliance, you are hereby notified that they are refused admission." Note that none of these four notices mentions the Import Alert, as the Import Alert merely provides factual information to help the district offices make the legal determinations.

In his Expert Report, Mr. Vodra put it this way at Paragraph 89: An Import Alert is neither a necessary nor a sufficient prerequisite for an import detention. FDA officials are authorized to initiate a proceeding whenever they find goods offered for import that do not appear to comply with the law. An Import Alert does not expand that authority. The Import Alert simply provides additional information to officers in the field. To initiate a detention hearing, an FDA official still must determine whether a specific shipment appears to violate the law. The Import Alert does not obviate any of the normal steps to complete the detention matter.

In its Reply, Apotex cites to a provision of the Code of Federal Regulations to suggest that the Import Alert had a legally significant connection to Apotex Corp.

The cited provision states, from the Reply: If it appears that the article may be subject to refusal of admission, the district director shall give the owner or consignee a written notice to that effect stating the reasons thereof. The Notice shall specify

1316

10:22:12 a place and period of time during which the owner or consignee shall have an opportunity to introduce testimony.

Apotex further quotes FDA's Regulatory Procedure Manual which states under the heading "Procedures When Violation is Found, The owner or consignee is entitled to an informal hearing before FDA in order to provide testimony in support of the articles." From these, Apotex concludes that the Import Alert has a legally significant connection to Apotex Corp. as the owner or consignee of the products being detained. But as I discussed, these provisions have nothing do with an Import Alert and nowhere mentioned Import Alerts. These provisions address the actual detention of the products, Measure Three.

To reiterate, Import Alert 66-40 simply provides information for determining whether a drug may be deemed adulterated for cGMP violations and, on that basis, refused admission to the United States. If the field office sees FDA's drug database that a facility is non-cGMP compliant or reviews a Warning Letter citing cGMP violations, then the field can

1317

10:23:28 detain drugs from that facility, regardless of whether the facility is on an Import Alert. In fact, we cited just such an example in our Rejoinder. Here's an e-mail with a subject line, "Import Hold of Teva Jerusalem Products" It says, "I'm holding four entries of imported finished product pharmaceuticals manufactured by Teva. The status tab mentions the issuance of a Warning Letter, but there is no with hold." In other words, the district office held four drug products based on the cGMP violations described in the Warning Letter issued to Teva, despite the fact that Teva was not on the Import Alert.

As Mr. Vodra has made clear, an Import Alert is neither a necessary nor a sufficient condition for an import detention. Apotex cannot transform FDA's nonbinding guidance into a legal Measure that prevented it from selling adulterated drugs in the United States. Nor can Apotex Corp. claim any legally significant connection to any Measure other than Measure Three, the Measure that actually detained drugs for which Apotex Corp. was the owner or consignee.

1318

10:24:40 In particular, Apotex's three arguments as to how the Import Alert specially affected Apotex Corp. are not persuasive. Apotex claims, first, that Apotex Corp. is the sole consignee of Apotex Inc. drugs for commercial sale in the United States. This claim, as we demonstrate in our pleadings, is not true. Apotex itself has submitted evidence showing other commercial consignees, including those we discussed in our Rejoinder of Paragraph 207. Apotex contends in its Rejoinder on jurisdiction that these consignees are different because they purchased drugs from Apotex Corp. directly, but that is legally irrelevant. Apotex itself acknowledges that the owner or consignee has a legal right to challenge the detention of drugs detained at the U.S. border, and thus, these other consignees are in no different position legally from Apotex Corp.

Second, Apotex argues that it was specially affected because the U.S. Measures cut off 80 percent of its drug supply. Those drugs, it observes, were manufactured specifically for Apotex Corp., as evidenced by the labels that Apotex has put into

1319

10:25:52 evidence. But what do these mean legally?

Let's take an example of another supplier of Apotex Corp. Apotex Corp. states on its Web site that it sources 24 of 30 sterile injectable products from Hospira India. That is, it sources four-fifths, or 80 percent, of its sterile injectable products from Hospira. Every label for every bottle sold in the United States will say "manufactured by Hospira Healthcare India and for Health Care Corp." as I have shown on the slide.

Apotex--FDA recently issued Hospira India a Warning Letter for cGMP violations at the facility that manufactures sterile injectables for Apotex Corp. According to Apotex, if FDA had put that Hospira facility on Import Alert, FDA would have cut off 80 percent of Apotex Corp's supplies for sterile injectables. By Apotex's logic--

MR. LEGUM: Mr. President, if I may interject briefly. What's being shown on the screen here is not in the record.

MR. SHARPE: Are you objecting to the introductions of a label from your product into this

10:27:07 Arbitration?

PRESIDENT VEEDER: If it's not in the record, you've got to tell us.

MR. SHARPE: Okay. Well, I note that this is from--I would direct the Tribunal's attention to the product list at 317.

PRESIDENT VEEDER: Okay. We'll come back to it later. For the moment, though, we're not going to look at this unless it has a record. We haven't asked you on each of these slides to identify the evidentiary record, but that's the reason we've got to be very careful. If it's not in the record, we don't want to see it.

MR. SHARPE: Thank you, Mr. President. We've endeavored to be careful in this regard, but we appreciate the additional guidance.

PRESIDENT VEEDER: Okay.

MR. SHARPE: If I might just put it in the abstract: If any company were to lose supplies from one of its suppliers because that company had gone on Import Alert, obviously that would have an effect on its business sales in the United States. The

10:28:00 question, I believe, is, what is the legal consequence of the fact that that importer in the United States sources these products from a foreign facility. None of the factors, we suggest, creates a legally significant connection between the Import Alert and Apotex Corp. We cite the Methanex Tribunal in this regard: A threshold, which could be surmounted by an indeterminate class of investors making a claim alleging loss, is no threshold at all. And the attractive simplicity of Methanex's interpretation derives from the fact that it imposes no practical limit.

Apotex proposes a rule that would protect an indeterminate class of investors. It cannot be the case that every time FDA issues an Import Alert for a foreign manufacturing facility, it exposes the United States to untold billions of dollars in investment claims from this indeterminate number of distributors to the United States. Apotex rightly criticizes Methanex as an extreme case, but in our view, this case is no less extreme.

Apotex's final argument is that the Import

10:29:08 Alert relates to Apotex Corp. because Corp. is part of a vertically-integrated group of companies, such that a Measure affecting one entity necessarily affects all others. As a legal matter, it cannot be correct that a Measure that affects one company affects every other company in a manner that is legally significant, even if those companies are part of the same corporate group.

I would take an example from Apotex's own group of companies. Apotex Holdings Inc. indirectly owns Starplex Scientific Corp., a Delaware company that makes plastic bottles for drugs made at Signet and Etobicoke. This is discussed in Apotex's Memorial. During the period of the Import Alert, Apotex could not export drugs from Etobicoke and Signet to the United States. Apotex Holdings thus, might have claimed damages on behalf of its U.S. enterprise, Starplex Scientific, which presumably lost revenue because it was not able to supply as many plastic bottles. But Apotex does not claim damages for Starplex Scientific in this arbitration and rightly so. The connection between the challenged

10:30:14 Measure, the Import Alert, and Starplex Scientific's bottle production is simply too remote to be legally significant for purposes of NAFTA Chapter 11.

Indeed, companies routinely structure their operations precisely so that Measures affecting one company are not legally significant to another company, whether for reasons of taxation, liability, or, as relevant here, jurisdiction. Thus, while Apotex highlights the corporate relationship between Apotex Inc. and Apotex Corp. in order to create jurisdiction in this case, when resisting jurisdiction in the United States courts, Apotex has argued that: The Court should not consider the corporate relationship between Apotex Inc. and Apotex Corp., which is not a parent-subsidiary in any event. Since Apotex Inc. alone is the only identified applicant, Apotex Inc. alone should be the only defendant.

Now, apparently recognizing this, Apotex stated in its Reply at Paragraph 176 that "Apotex did not suggest in its Memorial that the relationship between Apotex Inc. and Apotex Corp. was pertinent to the 'relating to' issue." To the extent that Apotex

recognizes that it should not conflate Apotex Inc. and Apotex Corp. for purposes of Article 1101 and Article 1139, then we could not agree more.

Mr. President, Members of the Tribunal, Apotex has failed to show any legally significant connection between the sole challenged Measure in this case, the Import Alert, and any alleged investor or investment. The Import Alert merely affects Apotex Corp. indirectly, incidentally, just as it affects scores of other companies that sell Apotex Inc. products in the United States. It would not be reasonable to infer, as Apotex suggests, that the NAFTA Parties subjected themselves to claims for billions of dollars in damages simply where foreign-owned investors alleged that particular Measures affect their business interests in the United States. Apotex's claims, we submit, cannot pass through NAFTA's jurisdictional gateway, and all of its claims should be dismissed on that basis.

Members of the Tribunal, that concludes our argument on jurisdiction, and unless there are further questions, I would ask that you call on Ms. Cate, who

will discuss the relevant facts.

PRESIDENT VEEDER: Thank you very much. No questions at this time.

MR. SHARPE: Thank you very much. We might need just a minute. Do we need a minute to change over the slides?

PRESIDENT VEEDER: Take your time.

MR. DALEY: Mr. President, just a small housekeeping matter. The next presentation has a fair amount of confidential information in it. We have consulted with counsel for Apotex. We think it would be far too complicated to keep turning on and off the feed every 12 seconds. So it's better to cut the feed for the entire thing.

PRESIDENT VEEDER: Do you have any comment about that on the Claimants' side?

MR. LEGUM: No objection.

PRESIDENT VEEDER: Well, I'm sorry for those who are listening in, but it's getting awkward. So we'll go into closed session for the next part.

Closed session, please.

SECRETARY TAYLOR: We're now in closed

session.

CONFIDENTIAL PORTION

MS. CATE: Mr. President, Members of the Tribunal, my name is Alicia Cate. Before our team presents the U.S. arguments on the Merits, I want to provide an overview of the most relevant facts for the Tribunal.

On Monday, you heard Apotex present its version of the facts. It is a version that downplays the undisputed fact that two of Apotex's Canadian pharmaceutical facilities had serious systemic manufacturing problems. It is a version that ignores Apotex's contemporaneous admissions of these violations. It is a version that overlooks the domestic laws in the United States and elsewhere around the world expressly permitting States to refuse to admit importation of products manufactured in those conditions. And it is a version that casts Apotex as a victim rather than the architect of self-inflicted problems.

The relevant facts have been briefed in great detail, and several FDA Witnesses have provided lengthy testimony. These Witnesses were the

10:36:10 investigators that inspected Apotex's facilities and the man who was involved in the decision-making at CDER concerning those inspections, Dr. Carmelo Rosa.

A consistent theme this week has been that FDA somehow rushed to judgment in finalizing the Import Alert recommendation. For example, the Tribunal may recall Apotex's assertion on Monday that: Consistent with FDA's newly announced policy of quick and visible action, Dr. Rosa noted that FDA was against the clock.

That is from Page 102 of the transcript, and it is in reference to Exhibit C-512.

Now, counsel for Apotex did not avail themselves of the opportunity to ask Dr. Rosa about that e-mail, even though they raised it in their argument quite prominently. But there was a question from the Tribunal about the documents. In response, Dr. Rosa explained that his use of the phrase "we are against the clock" in that e-mail was because of the realization that there were serious problems at both the Etobicoke and Signet facilities and that a lot of time had passed since the Etobicoke inspection. That

10:37:29 is from Pages 1073 and 1074 of the transcript.

This is just one example. We believe the record and the testimony is quite clear that FDA was thorough and deliberate in reaching its determination. The Tribunal has the record and has heard the testimony and can reach that conclusion for itself. We are confident that the Tribunal will review the entire record, so we don't want to take up valuable hearing time with a full recitation of the facts. Instead, I'd like to spend the next hour highlighting key documents in the record, which we believe are critical to the Tribunal's analysis of the Merits issues. As I proceed, I will address some of Apotex's mischaracterizations of these salient facts. But for the sake of time, I will not attempt to refute every point. Instead, I will address three main points.

First, I will describe some of Apotex's systemic safety and quality problems. Multiple inspections preceding the Import Alert in 2006, 2008, and 2009, demonstrated many significant, systemic cGMP violations at Apotex's Etobicoke and Signet facilities. Because of these systemic failures to

10:38:54 operate within Current Good Manufacturing Practices, the United States could, under well-established law, detain and ultimately refuse the admission of drug products from those facilities.

Second, I will address Apotex's failure to correct its systemic cGMP violations. Beginning in 2006 and continuing through to the period following the 2009 Signet inspection, FDA afforded Apotex numerous opportunities to allay the Agency's concerns about adulterated drugs reaching the U.S. market.

Following the Etobicoke inspection, Apotex vowed to correct its problems in a global manner, but the Signet inspection several months later revealed that no progress had been made. To the contrary, Signet suffered from the very same sort of systemic cGMP failures that Apotex had vowed to address several months earlier.

Faced with this reality and with little ability to trust that the promises Apotex made on paper would be implemented quickly in the factory, FDA placed Etobicoke and the Signet facilities on the Import Alert. Other regulatory agencies around the

10:40:19 world took similar action.

Third, I will address FDA's efforts to work with Apotex while the firm tried to remedy its cGMP violations. After adding Etobicoke and Signet to the Import Alert, FDA worked with Apotex as the company made efforts to remediate its manufacturing problems. FDA was in near-constant communications with Apotex and met with Apotex several times over the course of the next year. In fact, as Dr. Carmelo Rosa testified at Paragraph 77 of his Statement and again yesterday at Pages 1084-1085 of the transcript, the FDA has devoted countless resources in an attempt to bring Apotex into compliance with U.S. laws and regulations.

Ultimately, when a re-inspection revealed that many, but not all, of the systemic issues were getting attention, FDA used its enforcement discretion to remove Apotex's facilities from the Import Alert in 2011.

Turning first to the FDA inspections of Etobicoke and Signet in 2006, 2008, and 2009, the evidence shows that at the end of each of these inspections, FDA investigators issued a Form 483

1332

recording cGMP observations. These forms provided Apotex with notice of its cGMP failures.

[redacted]

Etobicoke 2008, and Signet 2009 inspections, FDA investigators recommended OAI, or Official Action Indicated. As Mr. Bigge explained, OAI is reserved for only the most violative inspections.

At the end of each of these inspections, Apotex was afforded an opportunity to respond to FDA's observations and take action to bring its manufacturing processes into compliance. And at the end of each of these inspections, Apotex acknowledged the deficiencies and pledged corrective action, corrective action that was not forthcoming.

Now, I will pause here to remind the Tribunal of the purpose of the FDA's overseas inspections.

First, unlike domestic inspections, when FDA can show up with no notice and can stay as long as it deems necessary, foreign inspections must be planned well in advance and are relatively short. They give

1333

FDA a glimpse into the firm's systems. They cannot check everything and are not designed to check everything. You'll recall Dr. Rosa's testimony yesterday about how FDA's inspections are just a snapshot.

This is from Page 1085 of the transcript.

Second, the purpose of the inspection is not to test all of the drugs coming off the assembly line; rather, it is to assess the adequacy of the firm's systems. There are six distinct systems that FDA considers important: quality, production, facilities and equipment, laboratory controls, materials, packaging and labeling. However, the quality system provides the foundation for the manufacturing systems that are linked and function with it.

Ultimately, the FDA is relying upon those systems and the firm's own quality control procedures to ensure that drugs entering the United States are safe and effective. So when a brief inspection of a firm reveals multiple problems with multiple systems, especially with the quality system, the alarm bells

1334

sound.

You will recall Dr. Rosa's testimony about the importance of a firm being in control of its processes. That is from Page 1024 to 1025 of the transcript. Mr. Vodra made the same point in his discussion about the "closed-loop system." And that is from Pages 1108-1110 of the transcript. And with that background in mind, let's turn to the inspections of Apotex.

FDA inspected Apotex's Signet facilities from June 26 to July 13, 2006. Two FDA investigators performed the inspection and issued a Form 483 to Apotex Inc. management at the end of the inspection

[redacted]

Following the receipt of Apotex's response proposing corrective action, FDA, in its discretion,

1335

deemed the Signet facility "acceptable" on October 25, 2006. In its letter to the firm, FDA also stated, "It remains your responsibility to ensure continued compliance with Current Good Manufacturing Practices."

From November 20 to November 24, 2006, FDA conducted a directed inspection of Apotex's Etobicoke facility to investigate concerns involving two drug applications.

[redacted]

Investigators classified the Etobicoke facility as Official Action Indicated.

Apotex submitted its response to the Form 483 on December 21, 2006. FDA responded in April 2007 requesting further information, which Apotex submitted on May 10, 2007.

On July 6, 2007, FDA sent a letter enclosing the EIR to Apotex and noted that, based on Apotex's response, FDA's concerns appear to be satisfactorily

addressed. However, as FDA discovered two years later during the following inspection of Etobicoke, Apotex's Etobicoke manufacturing practices were still not in a state of control.

Apotex's Etobicoke facility was again inspected in December of 2008. Ms. Emerson, who testified on Wednesday, was the lead investigator. At the close of that inspection, FDA investigators issued a Form 483 Recording 11 observations, including the failure to transfer testing methods and the failure to follow proper cleaning and tagging procedures, among other issues. Critically, Apotex was cited again for failing to file Field Alert Reports, or FARs, in a timely manner. Apotex downplays these failures as mere paperwork violations. But you will recall Dr. Rosa's testimony on this point yesterday where he explained the wide range of critical issues FDA uses these Field Alerts for and why it is so important for the Agency to get them quickly, within three business days. That is from Pages 1044-1046 of the transcript. Indeed, you can see the seriousness in Apotex's own failures.

For example, Apotex documents submitted to FDA showed that Apotex knew that one of its antifungal drugs had been cross-contaminated with an antidiabetic drug. According to Paragraph 14 of Ms. Emerson's Witness Statement, "Cross-contamination presents a risk of allergic reaction for some patients; yet the firm did not submit a FAR to FDA until late 2007, 15 months after the issue was first identified." You will also recall her testimony on Wednesday where she explained this issue in more detail. That is on Page 701-702 of the transcript.

Turning back to the other problems beyond the Field Alerts, Apotex was cited for failure to have sufficient stability data with respect to carbidopa-levodopa, which is used to treat the symptoms of Parkinson's disease. Stability testing provides data on how a drug's potency and quality vary over time under the influence of different environmental factors. This data justifies the "use by" dates firms put on pill bottles.

Apotex had changed [redacted] for the drug, but failed to conduct the proper

stability testing for the finished product. So the firm couldn't show that the drug product it was shipping to the United States was stable and effective for the full two-year expiry date on its label.

Ms. Emerson explained in detail during her testimony that when she was [redacted] That is on Pages 725-727 of the transcript. [redacted]

Finally, as you will recall from Ms. Emerson's testimony, Apotex's high rate of batch failures was discovered during the 2008 inspection. The data Ms. Emerson collected, which showed 554 batch failures between 2006 and 2008, were submitted as an exhibit to the Establishment Inspection Report. More alarming, CDER later learned that it did not appear that Apotex was investigating the root causes of the failures as required by cGMP regulations.

This week you have heard Apotex assert that

it was not told of this issue until it got the Etobicoke Warning Letter. But Ms. Emerson discussed the failure to investigate the root cause of batch failures with Apotex management in the context of her review of Apotex's ANDA for a particular drug, a diuretic used to treat hypertension, congestive heart failure, and other illnesses.

As Ms. Emerson explained, Apotex's management acknowledged that if a batch passed, it was released; and if it failed, it was rejected. I would refer you to Paragraph 23 of Ms. Emerson's Statement.

At the close of the inspection on December 19, 2008, Ms. Emerson presented Apotex management with the Form 483. Apotex was on notice of the cGMP observations at that point. As stated on the 483, Apotex could make objections to the observations or explain its proposed corrective action to FDA. It chose to do the latter and on January 30, 2009, acknowledged FDA's findings and pledged corrective actions.

In the meantime, the FDA investigators prepared the narrative Establishment Inspection Report

1340

and their recommendations. The investigators recommended OAI, Official Action Indicated, including withholding of approval on all pending ANDAs. Both a regional supervisor and CDER ultimately endorsed this recommendation.

I will just pause here to remind the Tribunal of Dr. Rosa's testimony yesterday where he verified this. This is at Pages 1090-1092 of the transcript.

Once CDER received the inspectional package for Etobicoke, CDER became very concerned. CDER analyzed, in particular, the high rate of batch failures and collected data on over [redacted] Adverse Event Reports and almost [redacted] consumer complaints that FDA had received about Apotex's drugs, noting issues such as therapeutic lack of effect, contamination suspected, and foreign material unidentified, among others.

In light of these significant issues, CDER contemplated recommending that Apotex's Etobicoke facility be placed on Import Alert in spring 2009. CDER requested an analysis of whether doing so would create a shortage for medically necessary drugs.

1341

However, as you have seen in Exhibit C-502, CDER decided to hold off until they had a regulatory meeting with Apotex's management.

Now, there was quite a bit of discussion on this drug-shortage issue in Apotex's statements this week, questioning whether a drug-shortage analysis was ever done. We believe Dr. Rosa testimony makes the situation clear. He testified that the Agency's regular practice is to perform a drug-shortage analysis "before we pursue an advisory action or any action of an Import Alert." That is from Page 845 of the transcript.

He explained, "I will not get an Import Alert recommendation without being done by the Compliance Officer because the first thing I will ask is, 'Did you check with Shortage?'"

FDA also was aware that Health Canada intended to conduct multiple inspections of Apotex's facilities. CDER scheduled an inspection of Apotex's Signet facility and on June 25, 2009, issued a Warning Letter to Apotex detailing its concerns about what FDA found at Etobicoke. The Etobicoke Warning Letter

1342

noted significant deviations from cGMP regulations, including, but not limited to, the failure to thoroughly investigate the failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed, the failure to submit timely FARs, and the failure to follow labeling requirements.

The Warning Letter made clear that: If you wish to continue to ship your products to the United States, it is the responsibility of your firm to assure compliance with all U.S. standards for cGMP and all applicable U.S. laws and regulations.

The Warning Letter also explained that in light of the cGMP violations, FDA may recommend withholding approval of Apotex's ANDAs and that Apotex's drugs could be subject to refusal of admission under U.S. law.

The Warning Letter requested Apotex to respond within 30 days and specifically recommended that Apotex promptly schedule a regulatory meeting. FDA wanted to discuss the Agency's concerns regarding the products currently on the U.S. market, in

1343

particular, the product lots that were included on the list of rejected batches and on another list of products shipped to the United States.

This regulatory meeting took place on July 9, 2009. Apotex then submitted its response to the Warning Letter on July 17, 2009, acknowledging the regulatory violations listed in the letter and again pledging corrective actions.

I will pause here to address a couple of points that Apotex stressed in its arguments this week.

Apotex suggested that FDA made its decision about the Import Alert before it had even reviewed its response to the Warning Letter. I would refer you to Page 502 of the transcript where counsel asserted that FDA did not review Apotex's response until after the Import Alert was issued. Apotex appears to make this assertion because of a reference in one document to that response being under review.

But as Dr. Rosa explained, "under review" is a term used to reflect that a case has not been closed out, not that the information has not been looked at.

1344

10:59:47 To the contrary, that response was carefully considered. I would refer you to Pages 923-924 of the transcript.

Apotex also contends that FDA misunderstood Apotex's batch-failure data. This point was made in Apotex's Reply at Paragraph 57, its Supplement to the Reply at Paragraphs 18-20, and again on Monday at Page 92 of the hearing transcript.

In its July 17 response to the Warning Letter, [redacted] Apotex went on to suggest that only [redacted] of 554 batches were true batch failures. As Dr. Rosa explained in Paragraph 14 of his First Statement, however, Apotex's Response missed the point. FDA's primary concern, one that was explained quite clearly in the Warning Letter, was not merely the number of failures, but also the firm's failure to investigate them properly and ascertain the root cause of the failures. The Warning Letter is up on the screen.

As Dr. Rosa explained yesterday,

1345

11:01:20 investigation of root causes of batch failures is a critical component of a firm being in control of its manufacturing systems. Failure to investigate and learn the root causes is, as he put it, tantamount to "guessing and crossing your fingers that you can have a good test result." That is from Page 1025 of the transcript.

CDER had scheduled an inspection of Apotex's Signet facility in light of the serious deficiencies found at Etobicoke and the fact that both facilities operated under the same quality control management structure and had similar quality control procedures.

FDA scheduled four investigators, including two CDER Consumer Safety Officers with cGMP expertise, to conduct a two-week inspection at Signet from July 27 to August 14, 2009.

Now, before I turn to the findings of the Signet inspection, I will pause to comment on the portrayal of the Signet investigation as being controlled by CDER.

The implication seems to be that CDER had made up its mind to issue the Import Alert even before

1346

11:02:45 the Signet inspection began and sent Ms. Zielny along for this reason. I would refer you to Pages 99, 100, and 491 of the transcript for a flavor of this.

You have now heard the testimony about that inspection, and you can assess this for yourself. You heard Mr. Payne explain that he participated in a long conference call in advance of the inspection where people were deciding which of the 54 New Drug Applications submitted by Apotex should receive pre-approval inspections. Those are on Page 754, 755, 758, and 759 of the transcript.

This is a critical fact. If FDA had already decided to issue an Import Alert, why would it be spending so much time deciding which New Drug Applications to review and perform pre-approval inspections for? The answer, of course, is that it wouldn't, which demonstrates that nothing had been predetermined at all.

As for Ms. Zielny and her supposed bias, I will simply say that you heard and, no doubt remember well, Mr. Payne's testimony about the personality conflicts and "the sizzle." That is on Pages 790,

1347

11:04:15 791, 801, and 802-804 of the transcript. I think that testimony speaks for itself, so I will leave it there.

I will now turn to the results of the Signet inspection. As Mr. Payne explained in his Statement, at the end of the inspection, investigators recorded 17 observations on the Form 483 and noted 10 verbal concerns during the closeout meeting. The Form 483 states: If you have an objection regarding an observation or have implemented or plan to implement corrective action in response to an observation, you may discuss the objection or action with the FDA representatives during the inspection or submit this information to FDA at the address above. Rather than voice an objection to any of the observations made at the time, Apotex repeatedly acknowledged the regulatory violations.

I will review several of the most significant of these findings, as well as Apotex's contemporaneous acknowledgments of these violations as recorded in the Establishment Inspection Report.

First, FDA investigators recorded startling instances of contamination in Apotex's drugs in the

11:05:44 form of acetate fibers, adhesive glue, cellulose-based materials, fluorocarbons, hairs, metallic particles, nylon, polyolefins, and protein-based materials.

It appears that at least two batches of the drug product produced using the same batch of API, Active Pharmaceutical Ingredient, were ultimately packaged into finished batches and were released on September 9, 2008, and distributed to the United States market.

Second, FDA investigators observed that, yet again, Apotex was late in filing its Field Alert Reports. This failure impacted FARs from multiple Apotex facilities because of Apotex's reporting system.

I will just pause here to remind the Tribunal that the failure to file FARs, Field Alert Reports, at the Signet facility continued to happen even after FDA had stressed the importance of timely filings with the firm following the Etobicoke inspection. Apotex was on notice that FDA considered timely FARs to be a critical concern. It was raised with Apotex in 2006. It was raised again after the 2008 Etobicoke

11:07:23 inspection. It was raised in the Warning Letter.

Yet, after all this and after Apotex's promise, a promise on paper, to fix its system for filing Field Alert Reports, there were still examples of Field Alert Reports filed late at the Signet facility. The Signet 483 notes one example occurring as late as June 2009. This is Exhibit C-61 and at Tab 24 of the Joint Core Bundle.

Mr. President, Members of the Tribunals, [redacted] Both facilities were under the same quality assurance management.

So FDA is seeing promises on paper such as those spelled out in Apotex's January 30, 2009, Response to the Etobicoke 483, but FDA sees no follow-through, no progress.

Turning back to the violations found during the Signet inspection, FDA observed that Apotex submitted incomplete and inaccurate statements in connection with an ANDA for an anticonvulsant and

11:08:52 mood-stabilizing drug.

As noted in the Signet 2009 Establishment Inspection Report at Pages 48-59, Apotex submitted to FDA an ANDA supplement to indicate its new drug-processing method. Critically, the supplement failed to report that a reason for the new processing method was due to dissolution failures.

As Dr. Rosa observed in his First Statement in Paragraphs 29 and 51, if a drug does not dissolve properly in the stomach, the consumer will not receive the proper drug dosage, which could be fatal. When confronted with this issue, Apotex management acknowledged that the information provided to FDA in the ANDA supplement "was inaccurate and incomplete."

Fourth, Apotex was cited for failure to follow written procedures for the cleaning and maintenance of equipment. Similar cleaning failures were found during the Signet 2006 inspection as well as the Etobicoke 2008 inspection.

Fifth, investigators cited Apotex again for failure to investigate batch failures. [redacted]

11:10:27 [redacted]

So again, FDA is seeing the very same systemic problem with regard to batch failures at both Etobicoke and Signet.

The Tribunal will, of course, recall the testimony of Dr. Rosa on the critical importance of investigating batch failures. I would refer you to Page 1025 of the transcript.

Sixth, Apotex was cited for failure to implement adequate processes to prevent cross-contamination of its drugs. [redacted]

During the 2009 inspection of Signet, FDA investigators again discovered, three years later, that Apotex had failed to complete the cross-contamination monitoring program, noting the

11:11:46 ongoing deficiency of its control systems necessary to prevent contamination or mixups.

As Mr. Vodra and Dr. Rosa explained, these observations, which include observations in all six manufacturing systems, indicate that Apotex was not operating in a "state of control." It was not following its own quality assurance procedures, not investigating failures, and not implementing the required processes. I refer you to Pages 1115-1117 of the transcript and Paragraph 42 of Mr. Vodra's Expert Report. Under these circumstances, FDA could not be assured that the many millions of dosages released by Apotex into the United States were safe and effective.

At the close of the inspection, the FDA investigators presented Apotex management with the Form 483 and met with Apotex to discuss their findings.

As was always the case, Apotex had the opportunity to object to any of these observations or to provide a response to FDA. Apotex did not object, nor did Apotex explain why there had been a delay in implementing any of the global corrective changes that

11:13:14 it had previously promised to implement, such as Field Alert reporting, for example.

During the inspection, FDA investigators remained in regular contact with CDER. As a result, CDER was well aware in real time of the significant and recurring deficiencies. This is evident from Apotex's own e-mails from the Signet inspection, which evidence conversations that FDA investigators had with Apotex personnel on a daily basis to inform them of observations they were finding during the 14 days they were there. These internal e-mails can be found at Exhibits C-46, C-47, C-49, C-50, C-52, C-53, C-54, C-55, C-59, C-60.

At the close of the inspection, FDA investigators also requested Apotex management to contact CDER the next business day, on Monday, August 17.

Now, before we get to that meeting, I will just pause to comment on the suggestion we have heard this week, such as on Page 491 of the transcript, that FDA's procedures were circumvented by sending the Signet Form 483 directly to CDER and bypassing the

11:14:39 district office.

There is just no support for this allegation. Mr. Payne explained that it is common to send drafts of the 483 to CDER during an inspection. That is from Pages 761 to 763 of the transcript.

And he explained that the Final Inspection Report was sent up chain in the district office and to ORA for review. That is at Page 787 of the transcript.

And just to dispel any remaining doubt on this point, I would like to show the Tribunal the FDA document that clearly indicates the chain of approvals for the Inspection Report.

Lloyd Payne finalized the Report on September 17, 2009, and his supervisor, Sean Cheney in ORA's Dallas District Office, endorsed the EIR on October 6. The FACTS cover letter, along with the EIR and exhibits, the inspection package, were sent to CDER on October 6. Contrary to Apotex's claims, the normal processes were followed.

In short, Members of the Tribunal, four FDA inspections over three years had revealed many

11:16:03 serious, systemic, and recurring cGMP deficiencies at both Etobicoke and Signet; two facilities, both in Ontario, that were under the same quality management and operating under similar quality procedures. These deficiencies raised alarms within FDA about the safety and efficacy of Apotex's drugs being exported to the United States. As the 2009 Etobicoke Warning Letter made clear, the result of cGMP violations is that the drugs were deemed to be adulterated under U.S. law and could be refused entry into the United States.

These inspections and the Etobicoke Warning Letter provided Apotex with ample notice of FDA's concerns. After every inspection, Apotex had the opportunity to contest the cGMP deficiencies observed. Apotex contemporaneously acknowledged many of its deficiencies and pledged corrective actions.

Far from seeing some progress when it inspected the Signet facility in the summer of 2009, particularly in light of the commitments the firm had just made earlier that year following the Etobicoke inspection, quite the contrary was true. The same problems remained and new problems were revealed. It

was in this context that the FDA made its decisions concerning the Import Alert.

Turning to the second part of my presentation, Apotex had another opportunity to allay FDA's concerns about Apotex's numerous cGMP violations. On Monday, August 17, 2009, Apotex's management called CDER as requested. Several FDA representatives joined the call, including Dr. Rosa. Apotex was also represented by several officials, including Dr. Desai. FDA explained to Apotex, once again, the Agency's concerns about the firm's cGMP violations. FDA requested to know Apotex's intentions with respect to all products on the U.S. market.

Apotex acknowledged that there are deficiencies and noted that Apotex would be performing a voluntary recall on approximately 640 batches, representing approximately 148 SKUs--S-K-Us--or 42 molecules. Notably, this large recall was based solely on the first two observations on the Form 483. FDA representatives then inquired as to whether Apotex intended to continue distributing products. Mr. Desai responded, "Apotex does intend to continue

distributing."

Dr. Rosa expressly stated again FDA's concern about Apotex's decision to continue distributing in the U.S. market in light of the significant deficiencies. But Apotex insisted that it would continue to ship its products to the United States while it fixed its cGMP violations. The call made absolutely clear to FDA that Apotex had failed to grasp the seriousness of the situation.

Indeed, as Mr. Vodra noted in his Expert Report at Paragraphs 72-75, "The August 17 telephone call appears to have been the turning point for FDA. The Agency had considered adding Apotex to the Import Alert as early as April 2009 but had not implemented it."

He added that, "The company told FDA it intended to continue to distribute products into the U.S. market, relying on its current quality system, the system that the company and FDA agreed was deficient and needed remediation. In my experience, FDA would have interpreted Apotex's response as lacking a real commitment to drug quality."

The record shows that, when faced with serious cGMP violations, other companies voluntarily ceased operations while remedying the problem to ensure that their products did not injure consumers. This was a step Apotex was unwilling to take.

Following the August 17 call, CDER finalized the Import Alert recommendation originally drafted following the 2008 Etobicoke inspection to recommend that DIOP add the two Apotex sites to Import Alert 66-40.

As Dr. Rosa observed at Paragraph 29 in his Supplemental Statement and in his testimony before this Tribunal, "The violations found at Etobicoke and Signet facilities were very serious, as evident from the response of U.S., Canadian, and international health regulators. The public health risk was significant, as evident from the consumer complaints and Adverse Event Reports. The firm's prior history was troubling, as evident from previous inspections. Apotex's response to the violations was weak and unacceptable, and CDER did not have confidence that Apotex was operating in sustainable compliance with

cGMP. And the products Apotex manufactured at Etobicoke and Signet generally were deemed not medically necessary or in short supply."

The risk-based factors CDER considered in recommending that Apotex's facilities be added to the report are standard factors considered by FDA whenever making an enforcement decision. They also mirror the discretionary factors Apotex's own Experts have acknowledged, including the seriousness of the violation and the company's response, which in this case was wholly inadequate.

Dr. Rosa cleared the draft Import Alert recommendation on August 19, 2009. The recommendation noted the Signet cGMP violations at both Etobicoke and Signet and serious concerns regarding the firm's quality and production systems. CDER's recommendation also specifically mentioned the August 17 call with Apotex.

On August 20, CDER's Branch Chief cleared recommendation, as did CDER's Division of Import/Export, and the Division Director for the Division of Manufacturing and Product Quality, who

11:23:49 then sent it on to DIOP for review. Thus, contrary to Apotex's suggestion, multiple individuals within multiple offices at FDA reviewed and approved the decision to recommend that Apotex's facilities be added to the Import Alert.

Apotex's facilities were added to the Import Alert on August 28, 2009. On August 31, FDA district offices began detaining Apotex's drugs from the Etobicoke and Signet facilities at the border. In total, seven shipments of Apotex's drugs were detained without physical examination. In accordance with standard procedure, FDA district offices initially sent a Notice of FDA Action, Notice Number 1, to the filer, importer of record, and consignee explaining that the listed products were being held and providing FDA contact information. Once screened and detained without physical examination, FDA sent Notice Number 2 that expressly explained that listed products were being detained due to cGMP violations.

Notice Number 2 also apprised Apotex of its right to submit testimony in advance of any decision to refuse admission of the products to the United

11:25:23 States. Specifically, Notice Number 2 stated, "You have the right to provide oral or written testimony to the Food and Drug Administration regarding the admissibility of the articles or the manner in which the articles can be brought into compliance." Despite notice, Apotex did not avail itself of the opportunity to submit testimony.

On this point I would just like to note that, had Apotex felt its drugs were being manufactured in compliance with cGMP at any time during the Import Alert, Apotex could have shipped its drugs and contested their detention. It never did so.

I would like to address two key points that are prominent in Apotex's pleadings and presentations.

First, Apotex repeatedly asserts that it did not have a chance to propose corrective actions prior to the Import Alert. This was addressed in Dr. Rosa's First Witness Statement at Paragraph 23, and you have heard his testimony explaining what he meant. This is from Page 958 of the transcript.

Dr. Rosa explained, "The basis for this statement is the inspection of 2006 with significant

11:26:55 GMP violations where FDA trusted their response and accepted their response that they were going to correct the issues. The basis for that statement is in 2008, the inspections conducted in 2008. The basis for that statement was the inspection of 2009. The basis for that statement, of course, as well would take into consideration the August 17 communication. Apotex had ample opportunity to correct the issues. Apotex had ample opportunity to implement sustainable corrective actions because this is what the Agency has been dealing with. The firm has been unable to sustain a state of compliance and to make products that are in compliance with cGMP. This didn't start yesterday. This started in 2006, 2008, 2009, 2011, 2012, 2013. This is what we are working with.

And as for the suggestion that Apotex was only given a weekend to sort out the problems at the Signet facility, I will again point the Tribunal to Dr. Rosa's explanation, which is at Pages 969-970 of the transcript.

"We are not expecting by Monday to have a Corrective Action Plan. We are not expecting by

11:28:21 Monday they fix the house. That was not the objective of that request to ask them to call us."

He goes on to say that the purpose of the call was "to discuss with them and let them know that we are concerned with the issues that were uncovered during the course of the inspection. That was the objective of that call, to let them know that the Center for Drugs, the FDA, was concerned with these findings, and if they had thought of any measure that they would be taking to ensure that only product that met the quality standards would remain in the market."

And the point, Mr. President, the point, Members of the Tribunal, is that on this August 17 call, Apotex didn't say what its so-called comparators said in the same circumstances. It didn't do what Teva's head of compliance did, which was to pick up the phone, call FDA, and say that they wanted to, as Dr. Rosa explained, shut down the facility until they could get to the root cause of their problems.

That is from Pages 1032-1033 of the transcript.

Rather, right after conceding that it had

serious deficiencies with its systems, Apotex wanted to return to business as usual.

The second point I would like to address is Apotex's argument that FDA never told Apotex why it was put on the Import Alert. This is difficult to understand. FDA had been telling them for years of an ever-growing laundry list of systemic quality control issues.

Apotex received the Form 483 for Etobicoke in 2008 listing various GMP violations. During inspections in 2006 and 2008, FDA investigators verbally conveyed the regulatory violations to Apotex personnel and provided nonexhaustive lists of them on 483s. Apotex also received the Warning Letter for Etobicoke in June 2009. The Warning Letter detailed specific cGMP violations and specifically apprised Apotex that, due to these violations, its drug products could be refused admission into the United States.

Apotex received the Form 483 at the end of the Signet 2009 inspection, which included 17 very detailed cGMP observations. Apotex met with the FDA

investigators at the close of the Signet inspection to discuss these observations.

Apotex had a call with FDA on August 17 in which the observations were discussed. When Apotex saw the Import Alert on September 2, it must have seen that it was specifically for "drugs from firms which have not met GMP."

And then on September 4, Apotex received the Detention Notice, which specifically stated that Apotex's drugs were being detained due to cGMP violations.

For Apotex to claim now that it had no idea why it was added to the Import Alert is simply remarkable. We're not sure what more FDA could have done to inform Apotex of its cGMP violations and the possibility that its products could be detained and refused admission on that basis. Indeed, Apotex responded to the Signet 483 on September 3, 2009, and Apotex informed FDA that it took FDA's concerns very seriously and promised "global actions to improve effectiveness of our quality systems at all Apotex sites." On the same day, Apotex and FDA held a

telephone conference to discuss the Import Alert and the corrective action required of Apotex. Apotex did not deny its cGMP violations or protest the Import Alert.

On September 11, FDA met with Apotex to discuss the firm's compliance obligations in greater detail. FDA reiterated its serious concerns regarding Apotex's facilities, noting that "similar significant cGMP deficiencies" had been found at both Etobicoke and Signet and that "site-by-site reactive fixes do not appear to be an effective approach."

Apotex's senior management, once again, did not dispute FDA's cGMP findings. Indeed, Apotex Inc.'s President, Jack Kay, acknowledged that it was Apotex's "job, not FDA's, to make sure that our systems are acceptable."

Nor did Apotex question, let alone protest, having been placed on Import Alert. To the contrary, Apotex again acknowledged FDA's concerns, pledging to take corrective action, including by retaining independent consultants to conduct a Product Quality Assessment, PQA, on all U.S. products and a

comprehensive audit on all PQA facilities; reviewing its corporate functions with a view to overhauling its systems and complying with cGMP; independently verifying implementation of regulatory commitments and an action plan; and developing new protocols and action plans for FDA review.

On that first point, Apotex had already hired and brought to the September 11 meeting a cGMP consultant named Jeff Yuen. Mr. Yuen would assist Apotex in the coming months with its cGMP remediation. As I will discuss shortly, Mr. Yeun independently confirmed FDA's cGMP findings at Apotex.

In the fall of 2009, several other regulatory agencies worldwide expressed serious alarm at Apotex's cGMP deficiencies. For example, the New Zealand drugs authority, Medsafe, reviewed FDA's cGMP observations and deemed Apotex's manufacturing practices sufficiently troubling as to justify a total import ban of products from the two Apotex facilities. Given the seriousness of the problems at the Etobicoke and Signet sites, Medsafe demanded that Apotex immediately provide:

1368

11:35:54 1 One, a full justification as to why Apotex
2 should be allowed to continue to supply into the New
3 Zealand market. This would include all steps taken to
4 rectify the "serious failure of our quality systems"
5 and ensure that product made now is different than
6 what was being done at the time of the 483. This had
7 to be specific to the New Zealand products, and this
8 answer has to be focused on why they should not impose
9 an import ban.
10 Two, general overview of the New Zealand
11 products and how a risk is managed for those products
12 and why a withdrawal or recall of products on the
13 market should not be mandatory.
14 Apparently unsatisfied with Apotex's
15 response, Medsafe placed an import ban on drugs from
16 the Etobicoke and Signet facilities. Medsafe also
17 publicly announced that it was "working closely with
18 other regulatory authorities and Apotex to obtain
19 assurance that issues identified in the FDA audit have
20 been resolved by Apotex." Medsafe made clear that its
21 import ban would remain in place until it was
22 "satisfied that Apotex had improved its manufacturing

1369

11:37:27 1 practices."
2 Similarly, Australia's drugs authority, the
3 Therapeutic Goods Administration, or TGA, imposed on
4 Apotex Australia the following nonnegotiable demands:
5 One, suspend all shipments of products
6 manufactured by the Signet and Etobicoke sites for
7 Australia with immediate effect until Health Canada
8 has completed its review of the Signet site. And
9 initiate a voluntary recall of [redacted] batches which
10 were tainted with a green color.
11 TGA specified that it would allow Apotex to
12 ship to Australia only when "Health Canada is okay
13 with the plans that Apotex HQ has put in place" to
14 remedy the various cGMP deficiencies.
15 The Netherlands Health Inspectorate, IGZ,
16 acting as a supervisory inspectorate for the European
17 Union, requested Apotex to temporarily cease the
18 import and distribution of all products imported in
19 the European Economic Area manufactured at the two
20 sites, with the exception of one drug considered to be
21 an essential product by some European Union Member
22 States. The IGZ also thus imposed a near-blanket

1370

11:39:00 1 import ban on Apotex products from the Etobicoke and
2 Signet facilities.
3 Members of the Tribunal, in no instance has
4 Apotex shown that any of these other regulatory
5 agencies--Medsafe, TGA, or the IGZ--provided Apotex
6 with procedural rights before acting to prevent the
7 importation of Apotex's drugs.
8 These foreign regulatory agencies were
9 sufficiently concerned that they also conducted an
10 informal visit of Apotex's facilities in
11 November 2009. At the conclusion of the visit,
12 Dr. Desai succinctly reported the international
13 agencies' conclusion to Bernard Sherman, "Our quality
14 systems lack quality."
15 Meanwhile, Health Canada launched rigorous
16 inspections of Apotex's Signet and Etobicoke
17 facilities and agreed to hold monthly teleconferences
18 with other national drug agencies to advise them of
19 the state of Apotex's compliance.
20 Health Canada's inspection took over a month
21 and involved 14 investigators. At the end of the
22 Signet inspection, Health Canada recorded 26 separate

1371

11:40:29 1 observations, including 18 Risk 2 observations--that
2 is, major observations--and four repeat Risk 2
3 observations.
4 At the end of the Etobicoke inspection,
5 Health Canada recorded 26 separate observations,
6 including 19 Risk 2 observations, and four repeat
7 Risk 2 observations. As a result of these findings,
8 Health Canada could have designated both facilities as
9 noncompliant potentially leading to suspension or
10 termination of Apotex's establishment license.
11 Apotex's did not dispute Health Canada's
12 objections at the time. To the contrary, Apotex
13 acknowledged the observations and committed itself to
14 addressing them and the system deficiencies
15 highlighted by them.
16 Apotex relies heavily on the fact that Health
17 Canada did not designate its facilities as
18 noncompliant at the close of these inspections, but
19 this reliance is misplaced. And, if anything, Health
20 Canada's reactions reinforces precisely why FDA's
21 actions here were fully in accord with the NAFTA's
22 provisions. And this is because Health Canada is the

national regulator. Like FDA, when it's dealing with facilities located in the United States, Health Canada had a large set of tools at its disposal to monitor Apotex and impose conditions on them short of a product ban. Health Canada took different actions than FDA because Health Canada was dealing with a domestic facility. It had more options, and it exercised them.

And we see this with Health Canada and Apotex. Health Canada imposed a series of extraordinary terms and conditions for the issuance of Apotex's 2010 establishment license, which remained in effect throughout the calendar year. Some of these conditions required Apotex to:

Submit weekly written reports--progress reports to Health Canada;

Conduct full investigations of batch failures to determine the root cause of the events and the impact of the event in relation to the manufacturing process, the batch in question and other batches which are currently in process and on the market;

Submit monthly updates of any such

investigations. In this connection, Health Canada specifically prohibited Apotex from reworking commercial batches, putting an end to Apotex's practice of retesting failed batches until they passed inspection;

Submit monthly progress reports on quality system improvements;

And submit to monthly site visits by Health Canada.

Health Canada's actions do not mean that it had no concerns about Apotex. To the contrary, Apotex does not dispute that, under Canadian law, Health Canada could only impose such conditions where there was a concern that the drugs were unsafe for use or where necessary to prevent injury to the health of consumers.

For Apotex to now summarize Health Canada's conclusions as merely compliant is thus disingenuous. The record shows that Health Canada was gravely concerned about the cGMP conditions at Apotex.

To sum up the second part of my presentation, the record shows that FDA provided Apotex with

multiple opportunities to correct its problems and allay concerns about adulterated drugs in the U.S. market.

When Apotex failed to allay FDA's concerns, FDA acted within its public health mandate and took enforcement action according to risk-based factors it applies equally to every drug company. As the record also shows, FDA's concerns were validated by the actions of other regulatory agencies worldwide, including the actions of Health Canada.

In the third and last portion of my presentation, I will briefly review FDA's efforts following the Import Alert through 2011 to work with Apotex and bring its facilities back into compliance.

Contemporaneous documents reveal that while Apotex had, in fact, made some progress in updating its quality systems, thing were far from perfect. Significant problems remained. But in recognition of the progress, and in light of Health Canada's close and continuous attention to Apotex, CDER exercised discretion and recommended removal of the facilities by the summer of 2011.

Starting in fall 2009, Apotex took several actions to try to right the ship. It [redacted] its Head of Quality Assurance, Lance Lovelock, and hired Ed Carey to replace him. Apotex also hired hundreds of additional quality assurance staff.

Under Jeff Yuen's supervision, Apotex developed a remedial plan for its quality control. In addition, Apotex regularly updated FDA on its progress. At no time during these conversations did Apotex ever object to the cGMP observations or the Import Alert.

I don't have time to review all of the teleconferences, correspondence, meetings between FDA and Apotex from August 2009 through 2011, but our Counter-Memorial, Rejoinder, and exhibits show numerous calls, e-mails, and meetings between FDA and Apotex throughout 2009 and 2010. I will just highlight a couple of points.

First, I will just mention the March 29, 2010, Warning Letter from FDA addressing the serious cGMP violations found at the Signet facility. As with the Etobicoke Warning Letter, it made clear that the

1376

cGMP violations resulted in Apotex's drugs being deemed to be adulterated under U.S. law, with the result that they could be refused entry into the United States. The letter requested that Apotex outline specific steps taken to correct the regulatory violations within 15 working days.

In the meantime, Apotex scheduled a regulatory meeting with FDA for March 31, 2010, in order to report on the firm's progress. In advance of this meeting, Apotex sent CDER a package of materials, including a quality assessment by its third-party consultant, Jeff Yuen.

The findings of this assessment were consistent with recent FDA inspectional observations and the recent Warning Letter citations and confirmed that "system-level improvements were needed for all six cGMP systems." At the regulatory meeting, Apotex again did not dispute FDA's cGMP findings, complain about either of the Warning Letters, or challenge the firm's addition to Import Alert 66-40. Apotex acknowledged the serious problems with its facilities and reported on the corrective action items that the

1377

company had resolved to take back in September of 2009.

Specifically, Apotex reported that a final Product Quality Assessment Report was not yet available for certain products; that 11 percent of the products tested had failed to meet established criteria; and that its quality systems assessments had identified deficiencies within and across all three of its Canadian facilities--Etobicoke, Signet, and Richmond Hill--as well as its Bangalore site in India.

Apotex also stated that it was committed to improving quality systems and to getting it right in order to quickly return to the U.S. market.

CDER cautioned Apotex that it had not yet made the required progress and instructed the firm to request re-inspection after it had resolved issues identified in the Warning Letters.

Although Apotex conceded that "the touchdown hasn't been scored yet," Apotex later thanked CDER for facilitating a "worthwhile" meeting and acknowledged that "the time and effort put in by everyone at FDA is very much appreciated."

1378

It was not until August 27, 2010, almost a year after the Import Alert was issued, that Apotex requested that FDA re-inspect its Etobicoke facility. In that letter, it requested a re-inspection in October. Apotex's request for FDA re-inspection of the Signet facilities was sent even later on September 29, 2010. Apotex did not specify a preferred date for that re-inspection.

The January and February 2011 re-inspections of Apotex's Etobicoke and Signet facilities were led by Mr. Goga. By the end of the Signet re-inspection, FDA investigators recorded 22 new or ongoing deficiencies on the Form 483. Some of these issues were previous observations from past inspections that still had not been fully corrected.

The observations included:

Failure to thoroughly review any unexplained discrepancy, whether or not the batch has already been distributed;

Failure to follow procedures to prevent objectionable microorganisms in drug products required to be sterile;

1379

The presence of an orange-colored powder, antibiotic, on testing equipment, a computer mouse, and a laboratory seat;

Failure to have certain quality control procedures in writing or failing to follow such procedures;

And failure to follow written procedures to prevent product contamination.

Dr. Desai acknowledged at the close of the meeting that Apotex still was "not meeting FDA's expectations." FDA investigators recorded five observations on the Form 483 for the Etobicoke inspection, including the discovery of brown material--later identified as cardboard--on the interior a screw cap being placed on the bottle of Apotex's drugs.

At the close of both inspections, FDA investigators presented the Form 483s to Apotex management. The investigators again recommended the facilities be classified as OAI, Official Action Indicated. They also recommended that FDA withhold approval of pending ANDAs and that the Import Alert be

1380

continued with respect to both facilities.

As in all previous inspections, Apotex was afforded the opportunity to contest any observations on the 483s. Instead, on March 1, 2011, Apotex acknowledged the cGMP violations and pledged additional corrective actions, while requesting that FDA lift the Import Alert due to Apotex's global efforts undertaken to improve quality control.

After reviewing the Etobicoke Form 483, Establishment Inspection Reports, Apotex's detailed response, and when considering the close attention that Health Canada continued to pay to Apotex's operations, CDER decided to downgrade the status of the Etobicoke facility from OAI, Official Action Indicated, to VAI, Voluntary Action Indicated. FDA informed Apotex on May 2011 that it would classify the Etobicoke facility as acceptable.

Three days later, on May 9, CDER sent a memo to DIOP recommending that the Etobicoke facility be removed from the Import Alert. On the June 14, 2011, DIOP accepted CDER's recommendation and removed Apotex's Etobicoke facility from Import Alert 66-40.

1381

With respect to the Apotex's Signet facility, FDA required additional information from Apotex on four specific observations. Apotex responded on June 10, 2011.

FDA also waited to receive the results of yet another Health Canada inspection of the Signet facility, which lasted 16 days in May to June 2011. Health Canada's inspection focused specifically on cGMP violations observed in FDA's January-February 2011 inspection and FDA's follow-up requests. Following a review of these materials, FDA notified Apotex on July 1, 2011, that it deemed the Signet facilities acceptable.

On the same day, CDER recommended that DIOP remove the Signet facilities from the Import Alert. DIOP accepted CDER's recommendation on July 29, 2011. As you heard Dr. Rosa explain, by this point, FDA was inspecting Apotex into compliance, and it continues to do so today. That is from Page 1019 of the transcripts.

Mr. President, Members of the Tribunal, these facts demonstrate that Apotex had numerous repeated

1382

cGMP violations over several years. Apotex never contested its cGMP deficiencies. Under the U.S. legal framework, FDA could refuse admission of Apotex's products due to these significant cGMP violations. FDA's findings were confirmed by Health Canada and other regulatory agencies around the world. Apotex was given repeated opportunities to demonstrate that it took these cGMP violations seriously, but failed to do so. FDA, therefore, placed Apotex on the Import Alert, and its products were detained and refused admission at the border.

FDA followed its usual procedures in doing so. There was nothing out of the ordinary. FDA lifted the Import Alert and continues to monitor Apotex's progress to this day.

As my colleagues, Mr. Bergman, Mr. Blanck, and Mr. Bigge will now address, these facts in no way support a claim under the NAFTA. Unless there are any questions, I would ask that you call Mr. Bergman who will address Apotex's claims under Articles 1102 and 1103.

PRESIDENT VEEDER: No questions at this

1383

stage. Thank you very much.

MS. CATE: Thank you.

PRESIDENT VEEDER: We're going quite well. It is 12:00. How long will the next section last?

MR. DALEY: I think it's quite long. If it's acceptable to everyone, my suggestion would be to break for lunch now. That will also give us the ability to consult briefly with Apotex on the slides for that presentation, which may enable us to be more efficient on the feed.

PRESIDENT VEEDER: That's a good idea. Is it possible we could cut lunch back from one hour? Would you mind if we did 45 minutes or 30 minutes even?

MS. GROSH: Mr. President, we have about 3 hours and 20 minutes.

THE PRESIDENT VEEDER: You haven't worked it out exactly.

MS. GROSH: I was just saying of argument left, and that would fit within. I think if we were to come back at 10 of 1:00.

PRESIDENT VEEDER: Let's come back at 10 to 1:00.

11:58:07 MS. GROSH: That would give us enough of a safety buffer.

PRESIDENT VEEDER: Let me just recite what the Tribunal has in mind. This has been discussed informally with counsel, but for the closing oral submissions, with the periods of time we're agreed, but not the sequence.

What the Tribunal is minded to propose is that we would start on Monday at 9:00 in the morning with the Claimant's Closing Oral Submissions, and they would run on. No doubt, the Tribunal would add to the time of 90 minutes, but we would certainly finish in good time mid-morning.

And then we would start with the Respondent's Closing Oral Submissions at 2:30 for 90 minutes. We would then break when that was over. Again, the Tribunal might add to the 90 minutes.

But we would break until Tuesday morning, when we would start at 9:00 for the Reply--and again, we stress it's a Reply--for both sides. But the Claimant would start at 9:00 for its 30 minutes, and then there would be a break; and at 12:00 the

11:59:13 Respondent would have its 30 minutes. We would anticipate finishing, obviously, before lunchtime.

Is that satisfactory? From the Claimants' perspective?

MR. LEGUM: Indeed, it is.

PRESIDENT VEEDER: From the Respondent?

MR. DALEY: Yes.

PRESIDENT VEEDER: It will be so ordered. We will back at 10 to 2:00. Thank you. 10 to 1:00. Sorry.

(Whereupon, at 11:59 a.m., the hearing was adjourned until 12:50 p.m., the same day.)

AFTERNOON SESSION

NONCONFIDENTIAL PORTION

PRESIDENT VEEDER: Respondent, you ready?

MS. GROSH: Yes.

MR. BERGMAN: Thank you, Mr. President, Members of the Tribunal.

First, a housekeeping matter. I don't believe we need to be in closed session. We've already identified with opposing counsel one particular slide near the end of my presentation that we'll have to close the feed for.

PRESIDENT VEEDER: If we don't need to be in closed session, let's keep it in open session as it is now, and when you come to the point, just tell us and we'll go into closed session.

MR. BERGMAN: Thank you, Mr. President.

Members of the Tribunal, it is an honor to appear before you today on behalf of the United States. I will discuss Apotex's failure to demonstrate a violation of NAFTA's Chapter 11 National Treatment and Most-Favored-Nation Treatment provisions.

12:52:52 Articles 1102 and 1103 are NAFTA Chapter 11's nondiscrimination provisions. Article 1102 sets forth an obligation of National Treatment.

On the screen you will see the provisions at issue: Article 1102(1), which concerns National Treatment for investors of another Party; and Article 1102(2), which concerns National Treatment for investments of investors of another Party. I will not read the particular language because we're all very familiar with it by now.

The National Treatment obligation is intended to level the investment playing field by requiring the NAFTA Parties to refrain from giving a competitive advantage to domestic investors or investments based on nationality of ownership. All of the NAFTA Parties are in agreement on the purpose of this obligation.

Canada has stated that Article 1102 prohibits treatment which discriminates on the basis of the foreign investment's nationality. Mexico has stated that Article 1102's focus is on the essential feature of the obligation; namely, the obligation to refrain from engaging in discriminatory treatment based upon

investor nationality which results in more favorable treatment to domestic investors. And the United States has stated the National Treatment provision was designed to prohibit discrimination on the basis of nationality.

I emphasize this point at the outset as it allows me to streamline my presentation. Despite putting in more slides than combined pages of both its Memorial and Reply, Apotex has not addressed nationality-based discrimination and cannot make the requisite showing.

Apotex does not dispute FDA's authority to have added Apotex's facilities to the Import Alert. Instead, Apotex contends that the United States breached NAFTA Chapter 11 by declining to put other companies with cGMP deficiencies on Import Alert or take an allegedly equivalent action by seizing products from or enjoining production at domestic manufacturing facilities.

As I will explain, Apotex has not established that it is sufficiently like, legally and factually, its alleged comparators. There can be no conclusion

that FDA's exercise of enforcement discretion on public health matters with respect to other companies such as Baxter, Hospira Inc., Teva Pharmaceuticals, and Sandoz Canada, discriminated against Apotex on the basis of its Canadian nationality. Instead, what is clear from the record, including hours of Witness testimony, is that FDA exercised its discretion rationally, in accordance with law, and in good faith.

The UPS v. Canada Award makes clear that to prove a violation of Article 1102, Apotex must demonstrate that Apotex Holdings or Apotex Inc. or their alleged investments: One, were accorded treatment by the United States with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments in the United States; two, were in like circumstances with the identified domestic investors or investments; and, three, received treatment less favorable than that accorded to the identified domestic investors or investments on the bases of Apotex's Canadian nationality of ownership.

Although Apotex previously acknowledged this

three-step analysis for its Apotex I and II claims, you heard Apotex argue earlier this week for a two-step analysis, relying on the Cargill v. Mexico Award. The relevant paragraph of the Memorial, which was relied upon by Apotex earlier this week at Page 224 of the transcript, is on the screen. But the Cargill Tribunal expressly contemplated another requirement. The Cargill Tribunal states, "A further requirement of Article 1102 is that the treatment must be with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments. The Tribunal will deal first with the like circumstances requirement. It will then address each of the two further requirements, in turn."

The Cargill analysis differs in order but not in substance from the U.S. approach. Consistent with the UPS Award, the United States simply requests that the Tribunal first assess whether Apotex has established if it has been accorded any treatment cognizable under NAFTA Chapter 11 before considering whether Apotex has established like circumstances and

less favorable treatment by reason of nationality of ownership.

Let me turn quickly to Article 1103. Article 1103 sets forth an obligation of Most-Favored-Nation Treatment. On the screen you will see the provisions at issue. Article 1103(1), which concerns Most-Favored-Nation Treatment for investors of another Party, and Article 1103(2), which concerns Most-Favored-Nation Treatment for investments of investors of another Party.

Establishing a violation of Article 1103 is the same as establishing a violation of Article 1102, except that the applicable comparator in the second step of the analysis is a foreign investor or its investments.

As the UPS Tribunal confirmed, failure by the investor to establish one of those three elements will be a fatal to its case. This a legal burden that rests squarely with the Claimant. That burden never shifts to the Party. I emphasize this point because Apotex has attempted this week and in its submissions to shift its burden to the Respondent, United States.

1392

12:58:51 In my presentation this afternoon, I will first begin by briefly showing that Apotex has not established that the Import Alert, the sole challenged Measure, accorded it any treatment cognizable under NAFTA Chapter 11.

Second, I will show that Apotex has not established that it was in like circumstances with its alleged comparators. In every instance, Apotex points to facilities entirely unlike Apotex Inc.'s Etobicoke and Signet facilities, which are located outside the United States, offered insufficient voluntary action, and produced only non-sterile oral solid dosages that were not in short supply.

Apotex's alleged comparators' facilities, by contrast, were largely located in the United States, took timely and sufficient corrective action, and produced different products, including short supply sterile injectable products.

Lastly, I will show that Apotex has not established that it and its alleged investments were sufficiently like the alleged comparators to permit any conclusion of less favorable treatment on the

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12:59:56 basis of Apotex's nationality of ownership.

Turning to treatment, has Apotex established that the sole challenged Measure accorded it the requisite treatment under NAFTA Chapter 11? When initiating its claim, Apotex acknowledged in the second paragraph of both its Notice of Intent and its Request for Arbitration that the Import Alert was adopted with respect to Apotex Inc.'s Canadian manufacturing facilities--two of Apotex's Inc.'s Canadian manufacturing facilities.

Apotex stated that on August 28, 2009, the U.S. Food and Drug Administration adopted a Measure with respect to two Canadian facilities operated by Apotex Inc.

Apotex Inc.'s Canadian manufacturing facilities, however, are not investments in the United States. Any treatment of those facilities by FDA does not qualify for NAFTA Chapter 11 protections. What little argument Apotex has provided on the treatment inquiry since then is circular.

Earlier this week, Apotex stated again its cursory argument on this point from its written

1394

13:01:02 submissions, and that's 321-322 of the transcript. In its Counter-Memorial on Jurisdiction, Apotex argued that "Apotex has established the requisite legally significant connection because the record shows that the Import Alert breached Articles 1102, 1103, and 1105 as concerns the investors and investments in question here."

In its Reply on the Merits, however, Apotex provided only two paragraphs, arguing that--in the highlighted portion--"The record amply shows that there was a legally significant connection between the Import Alert and Apotex Corp., Apotex Holdings, and Apotex Inc. Therefore, Apotex's case meets the first prong of the test under Articles 1102 and 1103, i.e., by adopting the Import Alert, the U.S. accorded treatment."

In other words, because Apotex has proven a breach under Articles 1102, and 1103, therefore, Apotex has established a legally significant connection for Article 1101, which itself establishes the treatment necessary for Articles 1102 and 1103.

Apotex's argument is entirely circular.

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13:02:12 It thus remains unclear how the sole challenged Measure, the Import Alert, accorded Apotex Inc.'s ANDAs and Apotex Corp. any treatment in the United States. As my colleague, Mr. Sharpe, explained, by Apotex's own admission, the ANDAs remained approved throughout the Import Alert and could have been licensed or sold to another company or transferred to another Apotex or third-party facility for continued production.

And it was not the Import Alert, Measure Two, that prevented Apotex from marketing drugs from Etobicoke and Signet in the United States. Rather, the reason that Apotex Corp. or any other company could not market drugs from those facilities in the United States is that those drugs appeared to be adulterated for cGMP violations, Measure One. On that basis, they were detained at the U.S. border and ultimately refused admission to the United States, Measure Three.

Members of the Tribunal, the Import Alert was, in Apotex's words, a mere temporary import advisory. It did not treat, as a legal matter,

1396

13:03:12 Apotex's ANDAs or Apotex Corp. in the United States in any way.

For these reasons, Apotex has failed to establish that it and its alleged investments were accorded the requisite treatment under Articles 1102 and 1103, and their claims must be dismissed. The Tribunal need not inquire any further.

Nevertheless, turning to the second inquiry, has Apotex established that it was in like circumstances with its alleged comparators?

Apotex and its Legal Experts wrongly assert that FDA Warning Letters for generic drug manufacturers during the 2008-2011 time period citing violations of the drug cGMPs provide for like comparisons. On Monday, Apotex confirmed that merely a finding of cGMP deficiencies places generic drug manufacturers in like circumstances, stating: "Apotex's National Treatment and MFN claims address differences in treatment of investments that depend for supply on facilities FDA found to be cGMP noncompliant. The fact that makes the circumstances like is the finding of noncompliance. Whether FDA was

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13:04:21 right or whether FDA was wrong in making any of those findings is not an element of the National Treatment or MFN claim here."

I would like to take a moment to address Mr. Crook's question in this regard from Wednesday morning about whether Apotex was still putting forward a one-size-fits-all approach to regulatory enforcement. This was on pages 247 and 248 of the transcript. And while it was stated by counsel to the Tribunal that a Warning Letter was just one of many circumstances that might be relevant to the like circumstances analysis, it is apparent that, in fact, the Warning Letter does still appear to be the distinguishing factor in Apotex's view. Despite the answers Apotex provided to your questions, what is on the screen is effectively the full extent of Apotex's like circumstances analysis. Apotex's Legal Experts pointed to other generic drug manufacturers that also received Warning Letters for cGMP deficiencies, asserting that, therefore, they are in like circumstances with Apotex.

As you can see on the slide--which I borrowed

1398

13:05:23 from Apotex's concluding presentation--Apotex embroiders a number of basic facts onto the issuance of Warning Letters about the pharmaceutical sector, alleged investments, and corporate structures. But it boils down, at bottom, to Warning Letters. And Apotex still ignores those circumstances actually relevant to FDA's exercise of enforcement discretion and wrongly tries to shift the burden to the United States.

Apotex's analysis on the screen cannot serve Articles 1102 and 1103's purpose of preventing discriminatory treatment on the basis of nationality. It is insufficient to permit the Tribunal to determine that but for Apotex's Canadian nationality of ownership, Apotex or its alleged investments would have received more favorable treatment from the State.

The most accurate way for the Tribunal to make this determination is to compare the treatment received by Apotex and its investments to the treatment received by a comparator that is like Apotex and its alleged investments in all relevant respects except for nationality of ownership. Then, if the treatment that comparator is receives is different, a

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13:06:35 presumption may arise that it was on account of a difference of nationality.

No such presumption can be made here. Apotex's reliance on Warning Letters alone to establish that Apotex and its alleged comparators are like in all relevant respects except nationality is wholly inadequate. It is also inconsistent with Apotex's concessions elsewhere in its submissions and its presentations, where it has expressly recognized that: The term "circumstances" denotes conditions or facts that accompany an action; it recognizes that investors and investments can be treated differently if the circumstances warrant; Apotex recognizes that NAFTA's nondiscrimination obligations allow some legitimate differences in treatment and do not bar legitimate regulatory distinctions; and, from earlier this week, Apotex's statement that the Parties are agreed that all circumstances must be taken into account in order to identify appropriate comparators."

Apotex, however, does not take all circumstances into account. I will focus, now, on three key issues and differences that Apotex has

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13:07:40 either downplayed or ignored and that the United States, contrary to Apotex's arguments, has never conceded. They are: (a), territoriality and the applicable legal regimes; (b) the circumstances that FDA considers in exercising enforcement discretion under its risk-based approach; and, (c), Apotex's non-sterile products versus its alleged comparators' sterile products.

Turning first to territoriality, Apotex claims that its Canadian facilities are in like circumstances with U.S.-based facilities despite the different legal regimes governing facilities inside and outside the United States. As the Grand River Tribunal noted, appropriate comparators are those that are subject to like legal requirements. After canvassing NAFTA Chapter 11 decisions, the Grand River Tribunal correctly stated: "While each case involved its own facts, Tribunals have assigned important weight to like legal requirements in determining whether there were like circumstances. The ADF Tribunal thus emphasized that both the Claimant and its U.S. competitors were subject to the same U.S.

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13:08:47 'Buy America' provisions.

"Pope & Talbot found the relevant comparators were lumber exporters subject to the same restrictive legal regime as the Claimant, so there was no denial of National Treatment if exports in other unregulated provinces were not so limited. Feldman v. Mexico found that the relevant comparators for purposes of MFN analysis to be a limited group of cigarette exporters subject to the same legal requirements as the Claimant. The Methanex Tribunal, citing Pope & Talbot, emphasized the importance of assuring that purported comparators face similar regulatory requirements.

"Looking at the question from the other direction, UPS v Canada found a key difference between the Parties there to be that Canada Post was subject to legal requirements under national law and international postal agreements that did not affect UPS."

In this case, Apotex's foreign facilities and its alleged comparators' domestic manufacturing facilities are not subject to the same legal regime.

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13:09:44 Domestic manufacturing facilities and their drugs cannot be subject to Section 801(a) of the FD&C Act, Import Alerts, or detentions without physical examination unless those drugs are first exported and then reimported.

Mr. Bradshaw explained the differences in the legal regimes between foreign and domestic manufacturing facilities as follows at Page 268 of the transcript: "The primary difference is that the FDA has an administrative tool that allows them to stop products at the border and to detain them under a standard that the products appear to be adulterated or appear to be in violation of the Food, Drug, and Cosmetic Act."

This territorial distinction found in Section 801(a) of the FD&C Act between drugs produced at facilities outside and inside the United States is a critical part of FDA's ability to protect U.S. consumers from violative products with limited resources.

Apotex wrongly asserted on Monday, at Page 235 of the transcript, that the United States has

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13:10:45 not provided a rationale for this legitimate regulatory distinction. But as Apotex acknowledged in Paragraph 15 of its Notice of Intent, as a Canadian drug manufacturer, Apotex is primarily regulated and controlled by Health Canada. FDA is not Apotex's primary regulator and it does not control Apotex's Canadian manufacturing facilities or any other private foreign manufacturing facilities.

FDA, moreover, does not have the ability to examine every import from foreign manufacturing facilities under its jurisdiction, nor can FDA closely monitor foreign pharmaceutical facilities seeking to export drugs into the United States. FDA cannot show up unannounced and conduct a thorough on-the-spot inspection. Instead, FDA has to trust and to rely on the management at foreign facilities to maintain comprehensive quality systems and to provide FDA with any Field Alert Reports regarding deficiencies in a timely manner.

Nothing in NAFTA Chapter 11 prohibits such a territorial distinction. To be clear, this distinction is not based on the nationality of the

13:11:55 trader who owns the manufacturing facilities, but on the location of those goods--location of those facilities and the goods that they produce. As Apotex recognized, the result of this distinction is that different considerations, including a different standard for establishing adulteration, applies to drugs produced at domestic and foreign facilities, and comparisons between those facilities are inapt.

Apotex's Memorial expressly acknowledged that Apotex was not subject to the same legal regime as U.S.-based manufacturing facilities, whether U.S. or foreign-owned. Apotex acknowledged that the form of enforcement action may vary depending whether the products are in the U.S. territory or offered for import. Apotex's Legal Experts elaborate on that location-based distinction stating that "FDA's primary enforcement tools for facilities located within the United States are Warning Letters, seizures, and injunctions. FDA's primary enforcement tools for facilities located outside the United States are Warning Letters, Detentions Without Physical Examination, and Import Alerts."

13:12:58 They then quote from the Agency's Guide to Inspections of Foreign Pharmaceutical Manufacturers, which states, "During the inspection of a foreign drug manufacturer, it is not necessary to obtain the same level of documentation expected from a domestic inspection to establish evidence of cGMP violations or data integrity problems. The Agency has the authority under the FD&C act to administratively restrict the importation of a product without demonstrating the adulteration of the product. The burden of proof is placed on the importing Party."

But Apotex's Experts omitted this next sentence, which is contrary to Apotex's troubling new assertion on Monday that FDA can adopt Import Alerts without any evidence, at Page 235 of the transcript. "However, the Inspection Report should contain sufficient information and documentation to support a conclusion by the reviewing office that significant violations of the law exist to warrant restricting importation of the commodity and/or nonapproval of affected applications."

Apotex accordingly admitted that while FDA

13:14:09 has the authority to detain imports that appear adulterated, it lacks similar detention authority for domestically produced goods that appear adulterated.

Apotex and its Experts acknowledged the different legal regimes governing facilities inside and outside the United States. With its Memorial, Apotex thus made clear that Apotex's alleged comparators' U.S.-based manufacturing facilities were not subject to the same legal regime as Apotex's manufacturing facilities. For this reason, the United States stated in its Counter-Memorial that as a threshold matter, the alleged comparators' U.S.-based facilities, both U.S. and foreign-owned, were in unlike circumstances and invited Apotex to identify appropriate comparators.

The U.S. Counter-Memorial also acknowledged that Sandoz Canada Inc. and Teva Pharmaceuticals Inc. were potential comparators because these were foreign manufacturing facilities. At the same time, we informed Apotex of the circumstances that FDA considers under its risk-based approach. Contrary to Apotex's repeated assertions, the United States has

13:15:14 conceded no other arguments.

With its reply, Apotex declined to reconsider its alleged comparators and invited the Tribunal to consider "less like" comparators. Instead, Apotex shifted tack. It claimed that facilities inside and outside the United States are subject to the same legal regime because FDA has ultimate authority to halt U.S. sales of drug products manufactured in violation of cGMPs.

But Apotex and its Experts acknowledge that for facilities outside the United States, whether U.S. or foreign-owned, FDA may administratively detain without physical examination and refuse to admit into the United States drugs that appear to be adulterated. By contrast, for facilities inside the United States, whether U.S. or foreign-owned, FDA was required to establish adulteration through judicial action--seizure, injunction--in order to bar drugs from the marketplace.

Apotex thus recognized that U.S. courts, not FDA, were the ultimate authority with respect to drugs produced in the United States. Apotex nonetheless

13:16:25 argues that the U.S. positions on treatment and like circumstances are inconsistent in two respects.

First, Apotex wrongly asserts that the United States's positions would have required a different result in the high fructose corn syrup cases. But Apotex ignores a key of fact of those cases. The high fructose corn syrup companies in Mexico were all U.S.-owned; and, thus, there were no domestic comparators. Those Tribunals concluded that a comparison to the Mexican sugar industry was appropriate under Article 1102.

Here, by contrast, Apotex ignores that there are both U.S. and foreign-owned companies in the United States supplied by facilities outside the United States that received a Warning Letter or was placed on Import Alert. In the words that Apotex's counsel used at Page 12 of transcript, there are U.S. companies, such as Pfizer, that depend for supply on--I'm adding a word here--foreign facilities FDA found to be cGMP noncompliant. There is no need to stretch the like-circumstances analysis to reach unlike comparators who have actually invested in

13:17:27 manufacturing in the United States.

Second, Apotex wrongly asserts that the U.S. argues for purposes of "relating to" and MFN/NT treatment that the Import Alert was mere guidance that afforded Apotex no treatment, and only the findings of GMP violations were relevant. For purposes of like circumstances, however, the U.S. argues that the cGMP findings did not make the circumstances like and the only pertinent measure was the Import Alert.

As you can see, Apotex offers no footnote for the first sentence, likely because there is no support for Apotex's characterization.

For the second sentence, Apotex's citation begins as follows, U.S. Rejoinder, Paragraph 222, "The U.S. Counter-Memorial similarly recognized the importance of the Import Alert...to Apotex's like-circumstances analysis."

Looking to Paragraph 222 for the accompanying text and italicizing the language that Apotex replaced with an ellipsis, it states--it's highlighted as well--it states, "In its Memorial, Apotex acknowledged that the Measure at issue (the Import Alert) and the

13:18:34 legal regime pursuant to which it was adopted is a key element of the like-circumstances analysis."

The U.S. Counter-Memorial similarly recognized the importance of the Import Alert and the related legal regime to Apotex's like-circumstances analysis. It pointed out, however, that products from facilities in the United States are never subject to Import Alerts or Detentions Without Physical Examination, and, therefore, U.S. facilities are not in like circumstances with foreign facilities such as Apotex's.

In other words, all manufacturing facilities are subject to cGMP regulations and possible cGMP findings, Measure One, but only foreign manufacturing facilities are subject to, under Section 801(a) of the FD&C Act, Import Alert guidance, Measure Two, and detention without physical examination for the appearance of adulteration, Measure Three.

Apotex, thus, has revealed no inconsistency in the U.S. position. To the contrary, Apotex has merely confirmed that U.S.-based manufacturing facilities are not subject to the sole challenged

13:19:37 Measure in case, nor are they subject to detention without physical examination and refusal of admission for the appearance after adulteration.

My colleague, Mr. Bigge, explained many other relevant differences. Domestic facilities, for instance, are subject to unannounced FDA inspections, whereas foreign facilities such as Apotex's usually receive advance notice. Domestic facilities, moreover, pay U.S. taxes, whereas foreign facilities, such as Etobicoke and Signet, may not.

The UPS Tribunal found such differences in legal requirements and responsibilities to be determinative, stating that "Extending no less favorable treatment to UPS Canada in like circumstances would require that the Heritage Department offer it the same arrangement as is offered to Canada Post; which would entail, among other things, the assumption by UPS Canada of the same responsibilities as those assumed by Canada Post under such an arrangement. However, that is manifestly not what UPS seeks."

The Tribunal determined that "In the

13:20:42 circumstances, we conclude that UPS Canada is not in like circumstances to Canada Post in respect of its program and, indeed, essentially for the same reasons, is not accorded less favorable treatment than Canada Post or treated differently because of nationality."

Although Apotex received advanced notice of its inspections and avails itself of Ontario's comparatively low corporate tax rate, Apotex asked to be treated as if its manufacturing facilities were in the United States. But as the Apotex I and II Tribunal observed, Apotex could, of course, have invested in U.S.-based manufacturing, development, or testing facilities, but opted instead to create and manufacture its generic pharmaceuticals in Canadian factories. Apotex confirmed that it had a U.S.-based facility manufacturing injectable products in Chicago, but it opted to close that facility in 2004.

Apotex has identified as comparators U.S. and foreign-owned manufacturing facilities in the United States, while the Apotex facilities at issue are in Canada. The Tribunal should reject Apotex's attempt to masquerade as a U.S.-based manufacturer. Apotex

13:21:54 and its alleged comparators' U.S.-based facilities are not subject to the same legal regime and those claims fail on that basis alone.

The second key issue I would like to discuss under the like-circumstances inquiry concerns the circumstances that FDA considers in exercising discretion under its risk-based approach. As I mentioned in my overview, in its Reply, Apotex's concedes that the term "circumstances" denotes conditions or facts that accompany an action, and that its alleged comparators can be treated differently if circumstances warrant. Apotex nevertheless ignores the conditions or facts accompanying FDA's exercise of enforcement discretion, and ignores the circumstances that may compel nonenforcement in matters of public health.

Although Apotex has stated that it is not aware of FDA's alleged risk-based approach, Apotex's own Legal Experts highlight the factors that FDA considers when determining whether to bring an enforcement action.

When comparing Apotex to Teva, for instance,

13:22:53 Messrs. Bradshaw and Johnson ask: How Apotex's cGMP violations were more serious than Teva's; how the risk to consumers as a result of Apotex's cGMP violations was greater than the risk to consumers as a result of Teva's; and how Teva's response to the violations was superior to that of Apotex's; and whether any of the products implicated indicated were medically necessary or in short supply.

Messrs. Bradshaw and Johnson conclude in the next paragraph, Paragraph 48, asserting that based upon their review of the circumstances here, none of the factors that FDA considers when determining whether to bring an enforcement action suggests that Apotex is riskier than Teva.

Now, this is not the FDA's articulation of the factors it applies, though they are close. You have heard Dr. Rosa's Statement and you have heard his testimony about the risk-based approach that FDA takes when deciding whether to place a firm on Import Alert. I would refer you to Paragraph 20 of Mr. Rosa's First Statement and his testimony at pages 827-828, 1034, and 1037-38 of the transcript. We submit that these

13:24:06 factors must be taken into account in any like-circumstances analysis. And while we question the wisdom of asking Members of the Tribunal to act as scientific specialists and second-guess, years later, FDA's exercise of enforcement discretion which involved weighing complicated circumstances to make difficult determinations. If that is to be done, then we submit the factors that the Regulatory Agency itself applies must be taken into account. And this is where Apotex's arguments again fall short.

First, Apotex asks the Tribunal to presume that its alleges comparators' cGMP violations are as serious as Apotex's cGMP violations merely because they were issued Warning Letters without any consideration of FDA's factual findings in the numerous Forms 483s and Establishment Inspection Reports that Apotex requested during document discovery.

Apotex itself does not offer much more, for example, asserting in its putative Rejoinder on Jurisdiction that the U.S. document productions contained Teva Jerusalem's Form 483 and EIR for the

2010 inspection, the 51-page EIR was produced twice. These two documents have not been submitted into evidence since they do not add anything new to what was already submitted about Teva Jerusalem's cGMP problems.

Apotex states that the 51-page EIR adds nothing to the Tribunal's analysis over a 3-page Warning Letter. This cannot be correct. But I invite you to review the Apotex 483s, EIRs, and Warning Letters in the Core Bundle to draw your own conclusions.

Second, Apotex provides little argument on how the risk to consumers from the alleged comparators' cGMP violations described in the Warning Letters was greater than the risk to consumers from Apotex's cGMP violations. Apotex cherry-picked among certain of its competitors' inspectional observations and asked this Tribunal to assume the role of FDA in evaluating the risk to its consumers of its competitors' products. And as Dr. Rosa testified yesterday at Page 1025 in the transcript, Apotex's quality systems at Etobicoke and Signet were not in a

state of control.

Third, Apotex provides little argument on how its responses to the cGMP violations were superior to those of its alleged comparators, who largely ceased or slowed production or limited distribution in a meaningful way. Instead, it argues that a company's voluntary action cannot be equated with State action. This argument misses the point. Obviously, a company's voluntary action is not the same as State action, but voluntary action can obviate State action. Voluntary action, thus, is an important part of FDA's enforcement considerations.

Apotex itself has acknowledged the importance of voluntary action in the enforcement context. Dr. Desai testified, for instance, that Apotex had concluded that a voluntary recall of products with which FDA had a concern over would alleviate a need for any enforcement action. But Apotex refused to suspend or limit distribution beyond one or two drugs from Etobicoke and Signet while implementing its corrective actions for deficiencies in every one of its six quality systems.

For Health Canada, however, Apotex took more drastic voluntary action. In response to Health Canada's October 2009 observation that Apotex was commingling toxic and nontoxic material at Signet, Apotex immediately committed to cease manufacturing any cytotoxic products at Signet. As a result, Health Canada recorded this observation in the second-highest rather than the highest risk category, which could have resulted in a noncompliant rating, potentially costing Apotex's Establishment license.

Fourth, Apotex ignores whether any of the products implicated by the alleged comparators' Warning Letters were medically necessary or in short supply. Because of medically necessary drugs and drug shortages, FDA occasionally refrains from enforcement action in order to avoid affecting such supplies.

As discussed on Thursday, FDA determined that Apotex did not produce any medically necessary or short-supply drugs. They further determined that adoption of the Import Alert with respect to Etobicoke and Signet would not create any sustained shortages.

Apotex gives drug shortages little attention

and has even tried to shift the burden to the United States to establish medical necessity. Apotex relies on a July 2012 letter in which U.S. Congress members urged FDA to ensure continued production of medically necessary drugs, particularly sterile, injectable drugs, despite ongoing cGMP problems at facilities makings those drugs. Indeed, as you can see on the screen, that letter specifically discusses Teva, Hospira, and Sandoz.

The only other company discussed in that letter is Ben Venue, a U.S.-based manufacturing facility that, I stress, is foreign owned. The Ben Venue example underscores two important points. First, it shows the importance of FDA's enforcement discretion in the drug-shortage context, which is applied without regard to nationality of ownership. Two, it shows the extent of Apotex's nonconsideration of medically necessary drugs and shortages.

Apotex's Legal Experts, for example, assert that "It is remarkable that while the U.S. claims that FDA is a worldwide leader in regulating drugs for public health, FDA filed a complaint against Ben Venue

and entered into a consent decree only in late January 2013, over a year after Canadian and EU regulators imposed their respective bans on the firm's products. In our view, this shows that FDA is applying its discretion in an arbitrary manner."

But it is, again, Apotex, that ignores circumstances that FDA considered in applying its risk-based approach to Ben Venue. Apotex ignores that Ben Venue voluntarily shut down its facility in November 2011, even though FDA had been monitoring its production of drugs in critically short supply, such as an injectable chemotherapy drug. Ben Venue's voluntary shutdown led to a dire shortage in February 2012 of an injectable drug used to treat childhood leukemia and rheumatoid arthritis. And Health Canada's own August 2011 Import Advisory on Ben Venue made an exception for drugs deemed medically necessary to Canadian consumers. FDA carefully weighed potential risks for U.S. consumers against other public health considerations in light of all relevant circumstances.

Health Canada acted similarly in 2009

concerning Apotex, which is Canada's largest supplier of generic drugs. At that time, Health Canada was considering whether to revoke Apotex's Establishment License by weighing the need to enforce Canadian cGMP regulations with the need to avoid a national drug shortage in Canada.

Apotex largely ignores the circumstances accompanying FDA's exercise of enforcement discretion such as consideration of drug shortages and a company's voluntary decision to slow production for remediation. It is, for example, precisely this type of discretion that led FDA to place Apotex's Etobicoke and Signet facilities on Import Alert for cGMP violations in August 2009, while declining to place Apotex's Richmond Hill facility on Import Alert for cGMP deficiencies in 2010. Apotex has, thus, not even attempted to meet its burden to establish that it was in like circumstances in all relevant respects but for nationality, with its alleged comparators. Its claims are legally deficient and could be rejected for this reason alone.

The third key issue I will discuss under the

like circumstances inquiry concerns the products manufactured at various facilities. In its Rejoinder on Jurisdiction, Apotex argues that Etobicoke and Signet should not be compared to facilities that manufacture any active pharmaceutical ingredient, or API. In support, Apotex notes that FDA has a particularized guidance document for cGMPs for API production. Apotex's Etobicoke and Signet facilities exclusively produce non-sterile oral solid dosages.

As I noted, Apotex's comparators are mainly manufacturers of sterile injectables which have been in chronic short supply. Sterile products, as the name implies, are more difficult to produce than non-sterile products and also require their own particularized guidance document. Both the sterile product manufacturing guide and the API manufacturing guide are on the screen and in the record.

As noted in a recent Wall Street Journal article, "The injectables market has been dominated by a handful of companies, because making the sterile medicines is costly but returns are generally low. Prices typically run less than $4 a vial, though they

can run much higher, said Sanford Bernstein, analyst Ronny Gal. Unable to make a profit, several companies fled the market and some drugs had just one supplier. Then manufacturing problems, supply constraints, and Government scrutiny of aging plants in recent years forced remaining firms, such as market leaders, Hospira, Boehringer Ingelheim GmbH's Ben Venue Laboratories business and Novartis AG's Sandoz unit to shut down facilities or scale back production. The result was that the number of sterile injectables experiencing shortages jumped to 183 in 2011, from 23 five years earlier. The number of shortages fell to 48 last year, according to the U.S. Food and Drug Administration. Pfizer Inc. resumed production of some cancer injectables that were in short supply. Also, some plants that were closed due to problems reopened after undergoing upgrades."

Apotex's Etobicoke and Signet facilities do not compete with sterile drug manufacturers, particularly injectable manufacturers. This is confirmed by the Drug Shortage Analysis performed for Apotex. In Exhibit C-502, Hospira, Baxter, and

13:34:24 Perrigo are not listed as companies that may be able to ramp up production of Apotex's drugs.

From the comparators at issue in this case, only Pfizer, Teva, and Sandoz are listed. Apotex Corp., moreover, only markets sterile injectable drugs manufactured by third parties like Hospira. Thus, just as Apotex argues that it is not like manufacturers that produce even a bit of API at a particular facility, neither is Apotex like manufacturers that produce sterile injectable products.

In sum, there are key issues and differences between Apotex and its alleged comparators, including territoriality and applicable legal regimes; the circumstances that FDA considers when exercising enforcement discretion; and the products produced by the various facilities. For these reasons, Apotex has not established that it is in like circumstances with any of its alleged comparators.

The third and final inquiry for the Tribunal is: Has Apotex established that it was accorded treatment that was less favorable than that accorded

13:35:26 in like circumstances to the alleged comparators on the basis of Apotex's nationality of ownership?

Apotex generally makes five arguments that it was accorded in like circumstances treatment that was less favorable. Apotex, however, does not take nationality into account. Before reviewing the alleged comparators, I would like to provide some general comments on each argument, all which of fall far short of showing discrimination on the basis of Apotex's Canadian nationality.

To do so, I'll borrow one of Apotex's slides that we saw--or a portion it--that we saw quite a bit yesterday, and I'll try to avoid some of the repetitiveness.

First, Apotex generally alleges that it was added to the Import Alert while other companies were not, and that this constitutes less favorable treatment. As discussed, however, Apotex's allegation is divorced from the location of the facilities, the circumstances that FDA considers, and the drugs those facilities produce. Apotex's presentation of its claim, moreover, is inconsistent with its concessions

13:36:28 in this case.

In its Reply, it admits that Chapter 11's nondiscrimination obligations allow some legitimate differences in treatment, and do not bar legitimate regulatory distinctions. Thus, even if Apotex were to establish treatment that was less favorable for the alleged comparators' facilities that I'm about to discuss, Apotex still has not shown that the treatment was unwarranted by the circumstances, based on illegitimate regulatory distinctions or, most importantly, based on its Canadian nationality of ownership. To be clear, this burden never shifts to the United States.

Second, Apotex alleges that its products were banned from the U.S. market. Apotex's products were not banned, however. They were subject, upon shipment, to detention without physical examination.

Third, Apotex generally asserts that other comparators received more timely inspections. Apotex, however, does not account for the fact that Apotex failed to request re-inspections for either facility for over a year.

13:37:32 Fourth, Apotex generally asserts that the Important Alert was lifted--was not lifted in a timely manner, whereas FDA acted more quickly when making compliance determinations for other companies. Apotex's argument is premised on so-called "clean re-inspections" at both facilities in 2011. That, however, is far from the truth as demonstrated by inspectors' continued recommendation of OAI.

Fifth, Apotex alleges that it was not allowed to propose corrective actions before being added to Import Alert. But Apotex ignores that it had months to propose corrective actions for Etobicoke and to apply those actions to the Signet facility which shared the same defective quality systems. Apotex, moreover, was given the opportunity make commitments on the August 17 teleconference but it instead opted for what it called a "goodwill recall" of some products and a refusal to limit distribution in any meaningful way.

With this in mind, I will present each of the each comparators' particular circumstances accompanying FDA's exercise of enforcement discretion,

13:38:34 together with Apotex's allegation of less favorable treatment. As Apotex acknowledges, the full factual context is to be taken into account in assessing whether the treatment accorded is less favorable.

Apotex has not established that it is sufficiently like in relevant respects its alleged comparators to even permit the Tribunal to consider whether Apotex was discriminated against on the basis of nationality. Indeed, despite trawling through FDA's documents, Apotex has submitted no evidence that FDA discriminated against Apotex on the basis of its Canadian nationality.

Instead, those documents demonstrate that FDA acted reasonably and in good faith in what was, at best, a difficult discretionary exercise involving many different circumstances. We believe that it is inappropriate for the Tribunal to second-guess, years later, FDA's consideration of these issues.

But to the extent that there can be any comparator in like circumstances, the United States believes that Pfizer for Article 1102 and Ranbaxy for Article 1103 appears to be sufficiently like in

13:39:40 relevant respects for the Tribunal to conclude without any doubt that FDA did not discriminate against Apotex on the basis of its Canadian nationality.

After that, I will briefly discuss Apotex's U.S.-based comparators and its foreign-based comparators. For each, I will identify the significant legal and factual issues which make clear that Apotex cannot demonstrate that it was discriminated against on the basis of its Canadian nationality.

For Apotex's 1102 claim, the United States accepts the U.S. company Pfizer as a possible comparator. Pfizer has a U.S. subsidiary, Greenstone, and a U.S. division, Pfizer Injectables. Both distribute and market Pfizer and third-party products in the United States. Pfizer's Greenstone and Pfizer Injectables are to borrow Apotex's test from its Reply "supplied by facilities outside the United States that received a Warning Letter or was placed on Import Alert."

Apotex argues that Pfizer's relationship with these Indian facilities cannot be compared to Apotex

13:40:37 Corp.'s relationship with the Etobicoke and Signet facilities, allegedly repeating--repeatedly--alleging repeatedly that Apotex's Corp. and Apotex Inc. are affiliates. But Apotex's argument cannot be squared with its arguments outside of this arbitration, where it has denied that, quote, "Apotex Corp. is the United States marketing and sales affiliate for Apotex Inc.," has denied that, "Apotex Corp. and Apotex Inc. are the two arms of the same business group, operate in concert with each other, and enter into agreements with each other that are nearer than arm's length," and has denied that there exists "any facts showing a corporate relationship between Apotex Corp. and Apotex Inc."

Just as Import Alerts were adopted with respect to foreign facilities supplying Apotex Corp., Import Alerts were adopted with respect to foreign facilities supplying Pfizer's distribution entities. Pfizer's supplying facility Aurobindo's Hyderabad site had an inspection conclude on December 22, 2010, and an Import Alert was adopted with respect to that facility less than two months later, on February 7,

13:41:43 2011.

FDA did not issue a warning letter for cGMP violations at that facility until May 20, 2011. The Hyderabad facility's non-sterile products were removed from Import Alert 66-40 on March 27, 2013, and sterile products from that facility remain on Import Alert to this day.

Another Pfizer supplying facility, Claris Lifesciences' Ahmedabad site, was subject to a June 1, 2010, Public Health Alert providing notice of Claris's recall of certain intravenous bag products manufactured at the Ahmedabad facility. Apotex fails to acknowledge that this action, like that taken for Apotex, was taken before any reports of injuries.

Just two days before--two days later and prior to an inspection, an Import Alert was adopted with respect to that facility. FDA did not issue a Warning Letter for cGMP violations at that facility until November 1, 2010. The Import Alert was adopted with respect to the Ahmedabad facility before FDA's inspection and prior to the issuance of a Warning Letter or any response by the company.

1432

13:42:51 Factually, Pfizer's supplying facilities were, thus, subject to the same regulatory tool as Apotex Corp.'s supplying facilities: Addition of those facilities to Import Alert 66-40. Apotex's argument that fewer products from Pfizer's distribution entities portfolios were on the Import Alert does not alter the fact that the same action was taken.

Apotex trumpeted on Monday, at Page 72 of the transcript, its so-called "vertical integration business model" by which Apotex is able to increase efficiency and profitability. But there's risk for Apotex to the increased efficiency and profitability of closing its U.S. manufacturing facilities and consolidating manufacturing in foreign facilities.

When systematic cGMP issues arise at consolidated facilities and they need to be shut down for remediation, that consolidated supply is at risk. FDA cannot be held accountable for the consequences of Apotex's more efficient and profitable business model.

Thus, in both instances, application of FDA's risk-based approach reached the same result for

1433

13:43:56 Pfizer's supplying facilities as it did for those supplying Apotex Corp.

I have two additional points based on Apotex's Rejoinder on Jurisdiction which address Pfizer extensively as well as Apotex's presentation. First, both supplying facilities produce sterile products, which are not produced at Apotex's Etobicoke and Signet facilities. We have noted this dissimilarity on the slide. Second, Apotex also points out that Pfizer Injectables is a division of Pfizer and not a subsidiary. Apotex argues that, therefore, Pfizer Injectables is not appropriate for comparison under Article 1102. We have noted this on the slide as well, as this argument has implications for Apotex's other alleged comparators.

Admittedly, as set forth on the screen, Pfizer is not identical to Apotex. Nevertheless, Pfizer is a U.S. company that is sufficiently like Apotex for the Tribunal to conclude that Apotex was not discriminated against on the basis of its nationality.

For Apotex's Article 1103 claim, the United

1434

13:44:54 States believes that a possible comparator is Ranbaxy, an Indian company that was purchased a few years ago by a Japanese company. I note first that the relevant Ranbaxy manufacturing facilities are outside the United States. FDA's risk-based approach also resulted in the adoption of an Import Alert with respect to Rambaxy's Dewas and Paonta Sahib facilities, though they only produce some competing products.

Apotex argued at length earlier this week that Ranbaxy was not in like circumstances because Apotex never committed any criminal offense and was never placed on FDA's Application Integrity Policy. Here's Apotex's slide, and I'd like to add what Apotex omitted.

As the United States stated, with the omitted portions, Apotex acknowledges that FDA issued two Warning Letters to Ranbaxy and placed its Paonta Sahib and Dewas facilities on Import Alert 66-40 on September 16, 2008. At that time, Apotex further acknowledges Ranbaxy had not pled guilty to any criminal offense. It did not do so until May 2013.

1435

13:45:55 And was not on the Application Integrity Policy. It was not listed until February 2009.

Nevertheless, Apotex omitted those dates and asserted earlier this week, at Page 437 of the transcript, that FDA knew full well that was dealing with a felon when it placed Ranbaxy on Import Alert two months after in September 2008. But as noted, Ranbaxy did not plead guilty until May 2013.

Apotex argues that Ranbaxy received more favorable treatment because the Ranbaxy consent decree had to be reviewed and approved by an independent federal judge; whereas, FDA placed Apotex on Import Alert. But the facts do not support Apotex's argument. Ranbaxy voluntarily accepted the sweeping consent decree only after three years on Import Alert. By that time, Apotex's facilities, by comparison, were already off the Import Alert. Ranbaxy was thus subject, at least initially, to the same regulatory tool as Apotex.

Admittedly, as you can see on the slide, Ranbaxy is not identical to Apotex. Nevertheless, Ranbaxy is a foreign company with foreign

manufacturing facilities that is sufficiently like Apotex for the Tribunal to conclude that Apotex was not discriminated against on the basis of its nationality.

I will now turn to Apotex's alleged comparators with respect to the domestic manufacturing facilities. To be clear, the United States believes that this comparison is entirely inapt. That Apotex asserts its discrimination claims with respect to both U.S. and foreign-owned domestic manufacturing facilities makes clear FDA does not discriminate on the basis of nationality of ownership.

The United States, nevertheless, categorically rejects for a number of reasons Apotex's allegation that the Import Alert discriminated against Apotex's Canadian facilities while FDA did nothing to protect the public health from Baxter's, L. Perrigo's, Hospira's, Sandoz Inc.'s, and Teva Parenteral's U.S.-based facilities.

Apotex's argument that FDA did nothing suggests that absent seeking a court order to seize drugs or stop production at a domestic facility, FDA

takes no steps to protect the public health. By Apotex's logic, Health Canada, too, did nothing with respect to the Apotex in Ontario, but we know that is not the case. Health Canada considered revoking Apotex's Establishment License and put Apotex under close continuous, on-site, supervision for more than a year.

Contrary to Apotex's argument, FDA monitored and evaluated the circumstances with respect to Apotex's alleged comparators' facilities in the exercise of its enforcement discretion and, in that process, did not discriminate against Apotex on the basis of its nationality.

For Baxter's Jayuya and Guayama Puerto Rico facilities, in addition to the territoriality and risk-based approach issues, I first note that these Baxter facilities do not produce solid oral dosages. They produce sterile products, and the Guayama facility also produces API. Baxter committed to sufficient, timely, and fully implemented corrective actions, thereby allowing FDA to issue a closeout letter within a year of the initial inspections.

Apotex, by contrast, required more than a year even to request re-inspections, and what Apotex calls its "clean re-inspections" were found not to have responded to all of FDA's initial cGMP concerns.

Apotex uses its Rejoinder on Jurisdiction to put in a Warning Letter that was issued to Baxter regarding a Marion, North Carolina, facility and the Jayuya facility in May 2013, outside of what Apotex's Experts call the relevant time period of 2008-2011. Apotex asserts that this shows FDA's continued tolerance of Baxter's cGMP issues, but this is only Baxter's second Warning Letter for finished pharmaceutical drug products since early 2001. In that period, Apotex has received more Warning Letters for finished pharmaceutical drugs than Baxter.

As Apotex's recognizes, moreover, many of the other Warning Letters involve cGMP deficiencies for medical devices. Nevertheless, Apotex ignores the more than $500 million FDA order against Baxter in that regard. Apotex emphasized that this was a recall, but omits that it was an FDA enforcement action as set forth in R-187.

For Hospira Inc.'s Rocky Mount and Clayton, North Carolina, facilities, I would like to walk through one of Apotex's slides. First, Hospira is in the pharmaceutical industry. Second, consistent with Apotex's assertion regarding Pfizer Injectables, Hospira Inc. is not eligible for comparison to Apotex Corp. because it is Hospira Inc., and Apotex has not identified any distribution subsidiaries.

Third, Hospira Inc. is a leading sterile injectable manufacturer on the U.S. market.

Fourth, Apotex does not compete with Hospira on the U.S. market. In fact, Apotex Corp. markets sterile injectable products from Hospira's Healthcare India facility that recently received a Warning Letter in May of 2013. That facility, notably, supplies Apotex Corp.'s sterile injectable products.

Fifth and sixth, FDA did issue, based on inspections of Rocky Mount and Clayton, North Carolina, a Warning Letter for cGMP deficiencies.

Seventh, just to clarify, the Boucherville facility is a Sandoz Canada facility.

And eighth and ninth, FDA did not issue

13:51:24 Warning Letter to Hospira for its Austin, Texas, facility.

Now, I would like to update my slide accordingly to note that Hospira Inc.'s facilities produced sterile drug products, particularly injectables, not oral solid dosages like Apotex's Etobicoke and Signet facilities. Also, I note the point regarding the fact that Hospira Inc. distributes Hospira Inc.'s products and Apotex has not identified a distribution subsidiary.

Factually, Hospira Inc. committed 375 million to its remediation efforts, slowing production lines, and even temporarily shutting down both facilities. Hospira, moreover, produces medically necessary and short supply injectable drugs. Apotex, by contrast, refused to stop or even slow production of drugs that were not medically necessary or in short supply.

Now, I would just like to add two more points. If I can just take the Tribunal back to Baxter for a moment, you will remember that Apotex emphasized the number of Baxter's Warning Letters for cGMP violations, which included 10 Warning Letters for

13:52:22 cGMP violations for devices. Despite making that argument in its Reply at Paragraph 354, Note 558, Apotex emphasized that devices were entirely inapplicable when it comes to FDA's adoption of an Import Alert for devices from a Hospira subsidiary in Costa Rica. First, Apotex cannot have it both ways on this issue. And, second, the Import Alert demonstrates that the FDA has taken enforcement action against Hospira and adopted Import Alerts with respect to U.S.-owned manufacturing facilities abroad with cGMP deficiencies.

For Perrigo's Allegan, Michigan, facility, I first note that this facility also produces different products than Apotex's Etobicoke and Signet facilities, including sterile and liquid products. Perrigo pledged and implemented timely corrective action, but FDA nevertheless monitored the facility and withheld approval of Perrigo's requests for Export Certificates. This was not an option, by contrast, for Apotex's foreign facilities because FDA does not control any of Apotex's manufacturing facilities.

For Sandoz Inc.'s Broomfield, Colorado, and

13:53:29 Wilson, North Carolina facilities, Sandoz committed over 170 million to remediation efforts at these facilities as well as at Sandoz Canada Inc.'s Boucherville, Québec, facility, including slowing its production and changing its leadership. Again, Apotex, by contrast, refused to slow production of its drugs.

For Teva Parenteral's Irvine, California, facility, I note that this facility produces sterile injectable drugs, not oral solid dosages like Apotex's Etobicoke and Signet facilities. In this regard, I urge the Tribunal to review carefully Apotex's slides concerning Teva as they conflate violations between Teva Parenteral's Irvine, California, facility, which produces sterile injectables, and Teva Pharmaceutical's in Jerusalem, Israel, facility, which produces oral solid dosages. As you can see on the screen, we highlighted the dissimilarities between the Irvine and Jerusalem sites in comparison with Apotex.

Factually, Teva Parenteral shut down the facility in order to effectuate the firm's remediation plan even though the facility produces medically

13:54:32 necessary and short supply injectable drugs. Apotex, by contrast, decided not shut down its Etobicoke and Signet facilities which, in any event, did not produce medically necessary or short supply drugs.

The allegation that FDA did nothing with respect to these U.S.-based facilities is false. There are, moreover, simply too many legal and factual differences between Apotex and these comparators for the Tribunal to conclude that FDA discriminated against Apotex on the basis of Canadian nationality.

Lastly, I will now turn to Apotex's alleged comparators with respect to their foreign manufacturing facilities.

For Sandoz Canada Inc.'s Boucherville, Canada, facility, I first note that while it is actually a foreign facility, Apotex has not addressed the circumstances that FDA considers under the risk-based approach, and that facility does not produce competing products. In this regard, I refer you to Dr. Rosa's testimony yesterday, where he explained why FDA did not adopt an Import Alert with respect to Sandoz's Boucherville facility. That is at

Pages 1037-1038 of the transcript.

In addition, I call your attention to the fact that the FDA Warning Letter has no observations regarding Sandoz Canada's production of oral solid dosages. That is because, although Apotex's counsel argued otherwise on Tuesday on Page 375 of the transcript, Sandoz Canada does not produce oral solid dosages for the U.S. market. Apotex either downplays or ignores two key facts: First, Sandoz Canada offered to cease production and, in any event, ceased production temporarily and proceeded to slow it, as well as having committed over 170 million to remediation efforts as this facility as well as Sandoz Inc.'s Broomfield, Colorado, and Wilson, North Carolina, facilities. Second, this facility produced medically necessary and short supply injectable drugs, and it limited its distribution to the U.S. market to such drugs.

As Sandoz Canada's response to the November 2011 Warning Letter made clear, the firm expressed its intention at that time to temporarily suspend or discontinue the production of certain

products at the Boucherville site, most of which have alternatives in the marketplace, to prioritize production of most medically necessary products, and focus on the supply of critical medicines to the Canadian market.

Apotex wrongly asserts that Sandoz Canada voluntary action cannot have obviated the need for further enforcement action. FDA's decision, however, falls squarely within its regulatory discretion and reflects its legitimate need to assess the potential risk to consumers and the appropriateness of each company's response.

If could I request to cut the feed.

CHAIRMAN: Let's cut the feed.

SECRETARY TAYLOR: Feed is cut.

CONFIDENTIAL PORTION

MR. BERGMAN: Thank you.

Indeed, Apotex benefited from FDA's exercise of discretion when it had significant cGMP problems manufacturing sterile products at its Richmond Hill, Ontario, facility. By June 2010, FDA had received numerous FARs--or Field Alert Reports--from the Richmond Hill facility reporting contaminated sterile nasal and ophthalmic products which could cause mild, transient local irritation and has a remote probability of resulting in permanent impairment of a body structure or function. FDA considered adding the Richmond Hill facility to Import Alert. At that time, however, FDA opted not to do so.

For Sandoz Canada, there are simply too many differences for the Tribunal to conclude that, by comparison, FDA accorded Apotex less favorable treatment on the basis of its Canadian nationality.

Mr. President, we can turn the feed back on now.

PRESIDENT VEEDER: Back on now.

SECRETARY TAYLOR: Feed is now live.

NONCONFIDENTIAL PORTION

MR. BERGMAN: I will now turn to Teva. Specifically, Teva Pharmaceuticals' Jerusalem, Israel, facility. Again, while it is actually a foreign facility that produces some competing products, Apotex has not addressed the circumstances that FDA considers under the risk-based approach.

Although Apotex's Legal Experts acknowledge FDA's risk-based approach with Apotex's Reply, they assert that upon their review of the circumstances here, none of the factors that FDA considers when determining whether to bring an enforcement action suggests that Apotex is riskier than Teva.

But they do not take into account the following circumstances, as set forth in a contemporaneous e-mail. "The firm has made the decision to recall 30 lots involving 21 different drug products made at the Jerusalem facility. There is real concern about patient impact. These are chronic medications that patients won't have when they go to get their medications from the pharmacy (including common blood pressure drugs, cholesterol lowering

1448

13:59:47 drugs, diabetes drugs, arthritis drugs, antidepressants and other widely used medications.) We see the need for a teleconference with Teva as soon as possible to let them know the medical need for these and to work with them to keep manufacturing medically necessary drugs at the supply levels needed to meet the patient needs while fixing their problems (as long as benefit outweighs any potential risks).

"We don't see any product on the list that would not be impacting patients, and we are worried about the impact of any supply disruption at the Jerusalem facility. Teva has a very large market share for these products and acquired additional market share when cGMP issues occurred in recent years at other manufacturers making these drugs (Caraco, Ranbaxy, Apotex, Actavis, and KV)."

This e-mail makes clear that Teva was in circumstances unlike Apotex. The list of companies at the end also makes clear that FDA does not discriminate on the basis of the nationality of ownership. FDA took enforcement action against Caraco, Actavis, and KV Pharmaceuticals even though

1449

14:00:58 they were all U.S. companies at the relevant time.

Apotex wrongly asserted two procedural arguments regarding the e-mail on the screen in its Rejoinder on Jurisdiction. First, Apotex attempted to exclude the U.S. evidence on this point, which was in its possession when it filed its Supplement to Reply and was and still clearly is fatal to its case.

Second, Apotex argued both that the United States is invoking an affirmative necessity defense with respect to the Teva's Jerusalem facility, and that it cannot even invoke that defense because FDA allegedly contributed to the shortages. To be clear, the United States is not invoking a necessity defense. Such an egregious argument, if approved by the Tribunal, is inconsistent with FDA's ability to exercise its discretion in regulation of matters of the public health. It would also be inconsistent with Apotex's burden as Claimant to demonstrate that it is in like circumstances with its alleged comparators.

In addition to the medically necessary and short supply drugs, Teva Pharmaceutical Inc. offered to cease production, which caused concern and

1450

14:02:06 confusion among some at FDA. It was clarified, however, that the Jerusalem facility would not shut down but, in any event, Teva limited distribution of products from that facility for remediation. And for these facts, I would invite the Tribunal to review the testimony of Dr. Rosa yesterday at pages 1032-1034 of the transcript, where he describes a conversation with Teva's head of compliance and also explains why FDA concluded that it would not adopt an Import Alert with respect to Teva's facility in Jerusalem.

For Teva Pharmaceuticals, there are simply too many differences for the Tribunal to conclude that, by comparison, FDA accorded Apotex less favorable treatment on the basis of its Canadian nationality.

In conclusion, Members of the Tribunal, Apotex has failed to demonstrate any of the three elements required to prove a breach of National Treatment or Most-Favored-Nation Treatment: One, that treatment was accorded; two, in like circumstances; and, three, that it was less favorable on the basis of nationality of ownership. Apotex's claims,

1451

14:03:11 accordingly, must fail.

Unless there are any questions, I would now ask the Tribunal to call upon my colleague, Mr. Blanck.

PRESIDENT VEEDER: Thank you very much. No questions at this stage. We're going at a rapid pace.

Let's have a 5-minute break. We can even go to 10 minutes. Thank you.

(Brief recess.)

PRESIDENT VEEDER: Respondents, are you ready?

Claimants ready?

Let's resume.

MR. BLANCK: Good afternoon, Mr. President and Members of the Tribunal. My name is John Blanck. I have just a brief correction for the record. I would like to note for the record that there was an error in a citation in Mr. Bergman's presentation that we just finished. The reference is on Page 1400, Line 2, of the rough transcript. The citation given was to Paragraph 28 of Mr. Rosa's First Witness Statement. The correct citation is to Paragraph 20 of

Mr. Rosa's First Witness Statement and also Paragraph 28 of Mr. Rosa's Second Statement.

PRESIDENT VEEDER: Thank you. That's not a felony.

MR. BLANCK: I'd also like to note that the Parties have conferred and there will be one time where I'll be asking the Secretariat to the cut the feed, but it will be brief.

PRESIDENT VEEDER: Thank you very much.

MR. BLANCK: My name is John Blanck, and I will address Apotex's failure to establish a breach of Article 1105, which prescribes the customary international law Minimum Standard of Treatment.

Apotex asserts that there is a rule of customary international law of general due process that would have required FDA to provide Apotex with an oral hearing and other procedural rights before it prevented Apotex from continuing to export to United States drugs that were legally deemed to be adulterated.

Of course, the United States did provide Apotex with opportunities to challenge FDA's decisions

through various mechanisms, including a hearing right after Apotex's drugs were detained at the border. But Apotex chose not to pursue them.

I will discuss why this Tribunal should reject Apotex's arguments regarding a would-be rule of customary international law of general due process. The would-be rule, that Apotex argues disciplines internal administrative decision-making, has evolved from its Memorial to its Reply and, once again, to this hearing.

Regardless of where Apotex's arguments might eventually settle, none of Apotex's would-be rules set forth standards to allow States to know whether or not they are complying with customary international law as viewed by Apotex, and none of its rules are supported by State practice or opinio juris.

If any of Apotex's would-be rules really did exist, they would threaten the ability of States to protect the health of the public allowing, among other things, for exporters to continue exporting adulterated drugs to a State's territory while the exporter engaged in dispute resolution. Customary

international law requires no such thing.

My presentation will address four areas.

First, I will show that the scope of Article 1105(1) is limited to treatment of investments and that Apotex's claim may not be sustained because it alleges treatment of investors, not investments. As such, its Article 1105 claim fails as a matter of law.

Second, even if Article 1105(1) were amended such that it did apply to the treatment of investors, Apotex's claim would, nevertheless, fail because it has not established that any general rule of due process exists in customary international law.

I will show that Apotex has not carried its burden of showing that State practice and opinio juris require a State to provide any legal process prior to internal administrative decision-making, including the halting of importation of adulterated drugs into the State's territory.

Next, I will discuss the extensive legal process afforded to Apotex by U.S. law, all of which Apotex chose not to utilize.

And, lastly, I will discuss the implication for the NAFTA Parties if this Tribunal were to accept Apotex's invitation to create a new rule of international law.

Let me start with the first topic.

My discussion here will show that the text of Article 1105(1) explicitly limits its scope to investments; Apotex acknowledged in both its Memorial and Reply that the legal obligation in Article 1105(1) is limited to treatment of investments; notwithstanding that acknowledgment, the factual allegations set forth by Apotex in the Memorial and Reply are limited to treatment of investors; at the hearing, Apotex argued for the first time that the legal standard in Article 1105(1) should be construed to include treatment of investors.

Let me start with the text of Article 1105 itself. We've put the first two paragraphs up on the screen, emphasizing certain parts. And I'd like to start by reading Paragraph 1, since that is what Apotex alleges has been breached:

Each Party shall accord to investments of

1456

14:21:21 investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security.

As you can see, the ordinary meaning of the obligation in Paragraph 1 is that the obligation extends only to investments of investors of another Party. It does not extend to the investors themselves, but only to their investments.

That point is easy to see when one compares the obligation in Paragraph 1 of Article 1105 to the obligations undertaken in Paragraph 2, which I'll read:

Without prejudice to Paragraph 1 and notwithstanding Article 1108(7)(b), each Party shall accord to investors of another Party and to investments of investors of another Party nondiscriminatory treatment with respect to Measures it adopts or maintains relating to losses suffered by investment in its territory owing to armed strife, conflict, or strife. Paragraph 2 thus deals with a different obligation than Paragraph 1, and it contains a different scope as well.

1457

14:22:43 The Parties made a distinct choice to have the obligation related to armed conflict and strife apply to both investors of another Party as well as their investments. This contrasts with Paragraph 1, which only contains an obligation that applies to investments.

In the face of Paragraphs 1's explicit terms, Apotex has requested that the Tribunal disregard the express language of the NAFTA. However, we would note that Paragraph 1 of Article 1131, which we're putting on the screen, requires the Tribunal to decide disputes in accordance with the NAFTA. The Tribunal does not have authority to issue an Award for a violation of Article 1105(1) based on treatment to an investor, even if proven.

Apotex has good reason to ask the Tribunal to rewrite Article 1105. Apotex's factual allegations with respect to its 1105 claim are for treatment of Apotex as an investor, not its alleged investments.

Let's turn to Apotex's allegations of failure of due process. As you will see, they do not include either the ANDAs or Apotex Corp. within their scope.

1458

14:24:15 The Claimants do not allege that the ANDAs did not receive due process or that Apotex Corp. did not receive due process. Rather, they allege that Apotex, which comprises Apotex Holdings and Apotex Inc., the alleged investors, did not receive due process.

And I'll pause here to note that Page 1 of the Memorial and Page 1 of the Reply define the word "Apotex" to mean Apotex Holdings and Apotex Inc., but not Apotex Corp. or the ANDAs.

For example, in the first paragraph of its 1105 argument in the Reply, Paragraph 389, Claimants argue: Contrary to the U.S.'s assertion, Apotex has amply demonstrated that the U.S. denied Apotex's investments, the Minimum Standard of Treatment, compelled by NAFTA Article 1105. The U.S. failed to accord Apotex the due process required by customary international law and U.S. Treaty practice when imposing the Import Alert.

So you can see in that first sentence, Claimants acknowledge the correct standard in Article 1105, which is that it only applies to investments; and yet in the very next sentence, the

1459

14:25:42 Claimants make no allegations regarding those purported investments, but instead allege that Apotex, the investors--the alleged investors--did not receive due process.

Even if this allegation were true, which it is not, it is irrelevant. The allegation does not fall within the scope of Article 1105(1), and this is not simply a stray sentence, but, rather, is the consistent approach taken throughout both the Reply and the Memorial. The Claimants consistently set forth allegations regarding the alleged investors here, not regarding the alleged investments.

For example, in Paragraph 442 of the Reply, Claimants argue that: Apotex was deprived of notice or any opportunity to defend itself from being placed on Import Alert.

As you can see, the allegations here do not involve Apotex Corp. or the ANDAs. The allegations are limited to Apotex, meaning Apotex Holdings and Apotex Inc., the alleged investors.

Another example is at Paragraph 452 of the Reply, which reads: Not only did the U.S. fail to

1460

provide any procedural safeguard before the Import Alert was adopted, the U.S. also failed to provide any meaningful route for Apotex to obtain due process after the adoption of the Measure. Again, the allegations are limited to Apotex, the alleged investors. The alleged investments are not included.

A similar failing can be observed in Paragraphs 8 and 106 of the Reply. Paragraph 106 is particularly interesting. Claimants argue that: Similarly, the Memorial showed that the Import Alert was adopted and enforced against Apotex without even the barest trappings of due process required by customary international law.

This paragraph explicitly and correctly notes that the Memorial suffers from the same failing that the Reply does; namely, that the Memorial also only makes allegations with respect to Apotex, the investors. In the Memorial, Apotex begins its discussion of the application of its would-be rule to facts of this claim on Page 144 under the heading "The United States Denied Apotex Due Process." The paragraphs that follow allege that Apotex, not

1461

Apotex's alleged investments, were denied due process.

Good examples of this can be found in Paragraphs 472, 473, 475, 476, and 477, where the Claimants allege that a variety of procedural safeguards were not afforded to Apotex, the alleged investors, not the alleged investments.

The allegations set out in Paragraph 472 state that: The United States, one, failed to provide Apotex adequate information; two, failed to inform Apotex of the Center's proposal to adopt the Import Alert; three, never communicated with Apotex the nature and rationale of the proposal; and four, did not provide notice and information to Apotex. As you can see, the allegations all relate to Apotex, the alleged investors. None of these allegations relate to the alleged investments in this claim.

473, 475--Paragraphs 473, 475, 476, and 477 of the Memorial similarly set forth allegations about procedural safeguards with respect to Apotex, the alleged investors, and not about the alleged investments.

In an attempt to correct this obvious

1462

weakness in Apotex's 1105 claims, counsel stated on Day 2 of the hearing at Page 460 of the transcript that it had, in fact, alleged unfavorable treatment of Apotex's investments. But he could cite to only one paragraph for this proposition, that being Paragraph 470.

Let's take a look at Paragraph 470.

As you can see, Paragraph 470 makes no allegations of treatment of Apotex's investments. Instead, it alleges treatment of the alleged investors, which is alleged to have impacted the alleged investments. But an impact is not what Article 1105(1) requires. It requires treatment of an investment.

Apotex has not argued that due process was denied with respect to its ANDAs. As such, no Article 1105 claim can be based on its ANDAs. And with respect to Apotex Corp., as already noted, the alleged failures set forth by the Claimants do not encompass Apotex Corp.

The Claimants' allegations are that by inspecting two Canadian facilities, the Signet and the

1463

Etobicoke facilities, and adding them to an Import Alert without providing prior legal process, Article 1105 was violated.

But neither of these facilities was owned by Apotex Corp., directly or indirectly. The facilities were owned by Apotex Inc. Thus the placement of these two facilities on the Import Alert did not involve any treatment of Apotex Corp. Notwithstanding these factual allegations, Apotex appeared to understand, in both its Memorial and Reply, that Article 1105(1) only involves treatment to investments within its scope.

Apotex articulated this legal standard in its Memorial at Paragraph 455. Apotex writes--and I'll start quoting from the middle of the second line with "Article 1105." "Article 1105 does not define the standard of treatment by reference to the relative treatment accorded to a comparator. It requires, instead, that investments by NAFTA investors be treated according to a body of international law."

That final sentence is--that final sentence is Apotex's statement of the legal standard of Article 1105(1), and it is a correct one. To allege a

14:33:01 breach of this provision, one must allege treatment to an investment that falls below the body of law known as the Minimum Standard of Treatment. We were, thus, surprised to hear Apotex advance a new theory on Tuesday and argue that Article 1105(1) could somehow include the treatment of investors within its scope.

In this connection, Apotex asserted that--and I'll quote from Page 461 of Tuesday's transcript--"All Parties agree that Article 1105(1)'s requirement of fair and equitable treatment includes an obligation to accord basic due process."

This is, of course, not the United States's position. In both the Counter-Memorial and Rejoinder, the United States argued that Apotex did not carry its burden of proving that any general rule of due process exists. I just refer the Tribunal to Paragraphs 366-375 of the Counter-Memorial and Paragraphs 290-320 of the Rejoinder for these arguments.

In any event, Apotex then went on to argue that Article 1105(1) must be read to include treatment of investors, not just treatment of investments,

14:34:30 because under the definition of "investment" in Article 1139, "only the investment in Paragraph (a), an enterprise, has a juridical personality and, thus, is the only investment on the list that could receive due process." This is from Page 461 of Tuesday's transcript.

This argument is wrong. Article 1105 does not require due process be provided to the investments. Rather, it requires treatment be accorded to the investments, and treatment can be accorded to each and every investment on the list. Apotex's argument has no merit. Apotex's arguments regarding Article 1117, made on Wednesday at Page 566, fails for this reason as well. Apotex argued that Article 1117(1) shows that when the Parties wanted to limit a provision to address investments that had a legal personality, they knew how to do so.

But for Article 1105(1), the Parties did not limit the application of Article 1105(1) to investments with a legal personality. That provision requires treatment to all of the investments listed in Article 1139 be in accordance with the Minimum

14:35:59 Standard of Treatment. And as we noted, each and every investment is capable of receiving treatment.

Lastly, I would note this: If Article 1105(1) is read to require treatment to investors, and not just investments, then the obligation to provide full protection and security will not apply just to investments, such as factories, but also to individual investors as well, such as the owner of Apotex. Under this view, when Mr. Sherman is in the United States or Mexico, those States must provide him full protection and security. The NAFTA Parties did not agree to this.

To sum up, because Apotex has not set forth facts alleging treatment to its alleged investments, its Article 1105 claim fails as a matter of law.

I'd now like to turn to my next topic where I will show that, even if Article 1105(1) were amended so that it did apply to investors, Apotex has not carried its burden of proving any rule of customary international law exists that would discipline State conduct in this claim.

First, let me discuss some of the relevant

14:37:39 legal standards. As has already been discussed, NAFTA's Free Trade Commission, or the FTC, issued a formal interpretation of this text on the July 31, 2001. I will not read the FTC note, as it is part of the record at CLA-5. However, the interpretations by the FTC contain a number of implications relevant to the present claim.

As has already been discussed, the first is that when Paragraph 1 of 1105 refers to treatment in accordance with international law, it is referring to customary international law's Minimum Standard of Treatment, not other sources of international law, such as treaty law or general principles of law.

Along those same lines, the second point to be made is that the concepts of fair and equitable treatment and full protection and security, as used in Article 1105, do not require treatment in addition to or beyond that which is required by customary international law.

Some Bilateral Investment Treaties may include these terms as autonomous obligations, meaning that the Tribunal applies the terms without regard to

customary international law.

That is not the case with the NAFTA, and as such, Arbitral Awards discussing autonomous Treaty provisions are not helpful or relevant to interpreting Article 1105.

And the third point to be made is that the interpretation clarifies that neither a breach of another provision--of another provision of the NAFTA nor of another international agreement are relevant to determining whether there has been a breach of Article 1105(1) of the NAFTA. The only thing that is relevant is customary international law. There is no dispute between the Parties on these points. This can be seen in Paragraphs 456 and 457 of Apotex's Memorial and in Paragraph 438 of the U.S. Counter-Memorial.

The Minimum Standard of Treatment is an umbrella concept incorporating a set of rules that have crystallized over centuries and form part of the customary international law of State Responsibility for injuries to aliens. These rules seek to ensure that the treatment of aliens do not fall below a minimum standard.

In other words, the Minimum Standard of Treatment reflects an absolute standard, not a relative one. It provides a floor for the level of treatment that a State must provide. As long as the State's treatment does not fall below that floor, the Minimum Standard of Treatment has not been violated.

And these are points on which the Parties agree. The agreement is evident from Paragraphs 455 and 459 of Apotex's Memorial and Paragraph 439 of the U.S. Counter-Memorial. To prove that a rule of customary international law has come into existence which binds a State, one must prove two elements: first, general and consistent practice of States; and, two, one must also prove that such practice is adhered to from a sense of legal obligation.

This is the standard set forth in Article 38(1)(b) of the Statute of the International Court of Justice, and it's also something the Parties agree on. That can be seen in Paragraph 457 of Apotex's Memorial, including Footnote 642, and in Paragraph 352 of the U.S. Counter-Memorial.

As we explained in Paragraph 353 of our

Counter-Memorial, sufficiently broad State practice and opinio juris have thus far coincided to establish minimum standards of State conduct in only a few areas, such as the requirement to provide compensation for expropriation, to provide full protection and security, and to refrain from denials of justice.

And it is well established in international law that, in the absence of any rule of international law governing State conduct in a particular area, a State is free to conduct its affairs in that area as it deems appropriate.

We have discussed this principle in Paragraph 353 of our Counter-Memorial, including Footnote 852.

And because Article 1105 applies only to investments, only those Rules of State Responsibility relating to a foreign investor's economic stake or property interests inform the Minimum Standard of Treatment, as incorporated by Article 1105. We discuss this in Paragraph 351 of our Counter-Memorial.

Now that we've reviewed the legal standards involved in applying Paragraph 1 of Article 1105, I'd

like to take a look to see how some Tribunals have actually applied these standards.

As you will see, when Investor-State Tribunals have applied the Minimum Standard of Treatment, they accord a high degree of deference to States when it comes to regulatory decision-making.

For example, in another claim under NAFTA's Chapter 11, the S.D. Myers Tribunal stated that: When interpreting and applying the Minimum Standard, a Chapter 11 Tribunal does not have an open-ended mandate to second-guess government decision-making. Governments have to make many potential controversial choices. In doing so, they may appear to have made mistakes, to have misjudged facts, proceeded on the basis of misguided economic or sociological theory, placed too much emphasis on some social values over others, and adopted solutions that are ultimately ineffective or counterproductive. The ordinary remedy, if there were one, for errors in modern government is through internal political and legal processes, including elections.

Another NAFTA Tribunal has explicitly

1472

endorsed this view. The GAMI Tribunal observed: To repeat, NAFTA arbitrators have no mandate to evaluate laws and regulations that predate the decision of a foreigner to invest. The present Tribunal endorses and adopts the following passage from S.D. Myers, and then it quoted the passage from S.D. Myers, which I just read, so I won't repeat it.

And another NAFTA Tribunal, this time in the Thunderbird claim, adopted a similar approach. That Tribunal stated in the context of the Claimant's gambling operations in Mexico that: The role of Chapter 11 in this case is, therefore, to measure the conduct of Mexico towards Thunderbird against the international law standards set up by Chapter 11 of the NAFTA. Mexico has, in this context, a wide regulatory space for regulation. In the regulation of the gambling industry, Governments have a particularly wide scope of regulation reflecting national views on public morals. Mexico can permit or prohibit any forms of gambling as far as the NAFTA is concerned. It can change its regulatory policy, and it has a wide discretion with respect to how it carries out such

1473

policies by regulation and administrative conduct.

Indeed, the Thunderbird Tribunal went on to State that: It is not up to the Tribunal to determine how SEGOB"--the State regulatory authority--"should have interpreted or responded to the Solicitude"--Claimant's proposed business operation--"as by doing so, the Tribunal would interfere with issues of purely domestic law and the manner in which governments should resolve administrative matters, which may vary from country to country." It is against this legal landscape that the Tribunal constituted here today is being asked to evaluate the FDA's regulatory action with respect to Apotex.

I would now like to turn to Apotex's arguments regarding its views of customary international law. I will show that Apotex has failed to prove that the existence of any rule of customary international law that disciplines a State from taking internal administrative action without some form of due process, including in preventing the importation of adulterated drugs into its territory.

1474

During this part of my presentation, I will show that Apotex's arguments regarding its would-be rule of customary international law have changed from its Memorial to Reply, and then changed again during this hearing. I will also show that none of Apotex's would-be rules are grounded in relevant State practice. And, finally that Apotex has not established opinio juris for the State practice it has cited.

First, I'd like to address how Apotex's views on the content of customary international law have changed over the course of these proceedings.

In its Memorial, Apotex argued that a six-prong rule of customary international law governed the conduct at issue in this claim. But after the United States showed that Apotex's would-be six-prong rule was lifted nearly verbatim from a passage of a law school working paper discussing common law, not customary international law, let alone the Minimum Standard of Treatment, Apotex abandoned its would-be six-prong rule and in its Reply decided to advance a four-prong rule. It argued that this was a general

1475

one-size-fits-all due process rule that applies to administrative decision-making.

In the Rejoinder, the United States showed that Apotex had not shown that a single State in the world applied such a general one-size-fits-all rule. It showed that the term "due process" was a common law term and one that had never been understood to mean the same procedural safeguards had to apply in all administrative decision-making. To the contrary, what process is due varies under municipal law depending on the circumstances.

Thus, at the hearing, Apotex changed, yet again, its views on customary international law, appearing to disavow the one-size-fits-all rule and arguing that the prongs should be flexible and would vary depending on the circumstances. That said, Apotex did not provide any standards for how the prongs might vary from context to context.

Additionally, Apotex has added a fifth prong, a severity-of-the-consequences prong, which it asserted states must consider before making a decision.

1476

14:48:47 And it has also created a heretofore unstated exception to its rule, what I'll call "the imminent harm exception." It cited no authority for the exception, nor articulated the parameters of this exception.

As articulated by Apotex, there is no way a State could ever know whether or not it was complying with international law. Apotex's would-be rule contains no standard against which a State can measure its conduct to determine whether it is acting lawfully. Nor has Apotex alleged a rule that could be understood to set forth elements of an affirmative case that a Claimant would know it has to prove to establish its claim.

Instead, Apotex simply asserts that a variety of factors exist, without explain how and under what circumstances they would apply.

This is not the way international law works.

Let's consider all three would-be rules, starting with the would-be six-prong rule in the Memorial. Can you find that in Paragraph 466 of the Memorial.

1477

14:50:00 Thus--I'm reading Apotex's would-be rule: Thus the rule of law translates today into certain procedural requirements for the deployment of legal process that include, one, the right to hearing before a decision is made; two, the right to have the decision made in an unbiased and impartial fashion; three, the right to know the basis of the decision so that it can be contested; four, the right to reasons for the official's decision; and, five, the right to a decision that is reasonably justified by all relevant legal and factual considerations. And in order to make these rights effective, one must add: Six, the right to have the validity of the decision tested in a court of law. All these rights, pertaining largely to the category of procedural rights, are key elements in order to reach, in the end, a substantively sound decision.

As noted, the source of this supposed rule is a law school working paper, cited to in Footnote 656 of the Memorial. So let's take a look at what that working paper says. As you will see, Apotex has left out vital context about the source of the supposed

1478

14:51:22 rule.

We're now putting up the relevant passage from the working paper, highlighting the portions which are virtually identical to Apotex's purported rule for the Minimum Standard of Treatment.

I'll read this working paper's passage:

Judges of the common law family of legal orders presume that individuals whose interests are affected by decisions of the public officials who staff the administrative State have certain rights. The package of rights will depend on many factors, including the way in which this doctrine has developed in that particular legal order; the nature of the interest affected; the impact of the decision on the interest; and assuming the official is acting on the basis of authority delegated by statute, on what the statute actual prescribes. However, in the abstract, the package, at its fullest, may include the right to a hearing before the decision is made, the right to have the decision made in an unbiased and impartial fashion, the right to know the basis on which the official intends to decide so that it can be

1479

14:52:37 contested, the right to reasons for the official's decision, and the right to a decision that is reasonably justified by all the relevant legal and factual considerations.

All the rights, except for the very last one, are usually grouped into the category of "procedural rights." They pertain to the way in which the decision is made, in contrast to the last, which gives the individual the right to a substantively sound decision. And in order to make these rights effective, one has to add one more right to the package, the right to have the validity of the decision tested in a court of law.

As you can see, when the working paper was discussing these six rights, it was not discussing the Minimum Standard of Treatment or even customary international law. It was discussing common law.

Moreover, the working paper was not saying that these rights existed absolutely even amongst common law countries. Rather, the working paper said that the package of rights depended on many factors, and that, in the abstract and at its fullest, the

1480

14:53:52 package may include the six rights identified by Apotex.

Far from establishing a rule of customary international law, the working paper does not even establish general and consistent practice of common law countries. To the contrary, it explicitly states that the package of rights varies depending on the context.

Nor does this passage even purport to address civil law countries. The Tribunal will recall that on Wednesday, at Page 543 of the transcript, Apotex represented that civil law countries formed the majority of developed legal systems of the world. It is clear that this working paper does not establish the customary international law standard.

Perhaps realizing this, Apotex abandoned it in its Reply and replaced it with a new would-be rule, this time with four prongs. Apotex's second would-be rule purportedly applies whenever a State is deciding the rights and interests of the individual Parties in an administrative context.

When such is the case, Apotex argued that the

1481

14:55:07 State must satisfy the four following procedural prongs before it makes such a decision. I'll read these four prongs:

An impartial administrative authority; adequate information with respect to the nature of the proceedings so as to permit the alien to present his claim or defense; reasonable opportunity to contest evidence against him; and reasonable opportunity to obtain and present Witnesses and evidence in his behalf. This slide is Paragraph 439 of the Reply.

You'll see from the slide that Apotex states "Customary international law requires" that these four prongs be applied. Apotex does not state that these are factors which may or may not apply depending on the context. Apotex states that the four prongs are required. Apotex also discusses this would-be four-prong rule in Paragraph 390 of its Reply where it describes these prongs again, not as factors, but as black-letter law. Let's take a look at part of Paragraph 390.

When discussing this four-prong rule, Apotex has argued that "First, the U.S. errs in suggesting a

1482

14:56:35 distinction in customary international law between due process rights in administrative adjudication and in administrative decision-making. State practice, however, does not support the artificial distinction posited by the U.S. To the contrary, State practice and opinio juris require administrative authorities to provide procedural safeguards in proceedings of any kind that decide the rights and interests of individual persons. Those safeguards were recognized as black-letter law in the 1965 'Restatement of the Law Second Foreign Relations Law of the United States.'"

There are three points to be made here. First, regarding the first passage we highlighted, Apotex argued that international law requires the procedural safeguards for an administrative adjudication, such as one before an administrative law judge, to be the same as those for the thousands of nonadjudicative administrative decisions that get made on a daily basis regarding individual persons.

Apotex's argument was that every administrative decision a State makes must apply the

1483

14:57:53 same procedural safeguards before an administrative decision can be made, regardless of whether it was adjudicative or not.

Next, with respect to the second passage we've highlighted, Apotex argued that a State must apply these procedural safeguards for administrative decisions "of any kind." Thus the context of the administrative decision is not relevant under the Reply's would-be rule.

Under this theory, every administrative decision, including those from outside the drug importation context, would have to be made using the same procedural safeguards. Thus administrative decisions involving national security and public health would have to be undertaken applying the same procedural safeguards as decisions involving, say, whether to issue a building permit or a visa to a business traveler or whether to pardon someone convicted of a crime or whether to grant a property owner's request for a zoning variance or whether to issue a fine for an environmental violation that has already ceased.

14:59:11 According to the Reply, customary international law requires a State to make all these decisions while using the same procedural safeguards, regardless of subject matter and regardless of whether a State is making a decision regarding a threat that is imminent or ongoing or whether the threat has already ceased or even where no threat existed at all.

Apotex stated further at Paragraph 428 of its Reply that: While regulatory agencies may have some discretion as to the substance of the decisions in the interest of the community, no such deference exists with respect to the process by which those decisions are reached, which must always respect procedural safeguards. In order to preserve the strong presumption of regularity in administrative decisions, systematic application of procedural safeguards must be adhered to.

Once again, Apotex stated its view that while a State has discretion regarding the substance of administrative decisions, it does not have any discretion regarding the safeguards it applies for such decisions. There is no evidence that any State

15:00:29 operates like this. No authority supports such a radical rule.

Perhaps realizing this, on Tuesday it abandoned these arguments. I'll refer to Page 476 of the transcript where Apotex stated, "Now, as an initial matter, Apotex has never argued that customary international law invariably requires due process before a State may permissibly take an administrative decision with severe impact on an alien. Rather, Apotex's position is, and always has been, that the amount and timing of the due process depends on the context."

When considering the credibility of that statement, the United States urges the Tribunal to review Paragraphs 390, 428, and 439 of the Reply. Additionally, we would urge the Tribunal to consider Paragraph 466 of the Memorial where Apotex stated that all six rights of the Memorial were key elements to reach a substantively sound decision. In this paragraph, Apotex explicitly states a hearing is required before a decision can be made.

In any event, now that Apotex has walked away

15:01:55 from its would-be rules in the Memorial and Reply and argues that the amount and timing of its third would-be rule depends on the context, let us consider the context of this claim. The relevant context in this case is the importation of the drugs legally deemed to be adulterated. Yet Apotex's Memorial and Reply fail to introduce any evidence of State practice from this context that would support its rule.

Apotex's submissions failed to introduce evidence that even a single State undertakes the legal process identified in Apotex's would-be rule before the State undertakes administrative action in the protection of public health and safety, including preventing the importation of the adulterated drugs into its territory.

If States really did provide the legal process that Apotex envisions before a State could undertake such administrative action, one would expect to find these procedures in statutes, regulations, court decisions, or other authorities. As both the Counter-Memorial and the Rejoinder pointed out, Apotex had not identified any such authorities.

15:03:12 What is so striking about Apotex's arguments is that it avoids discussing any authority from the drug importation context. In this case there is evidence of State practice from this very context.

In Paragraph 45 of his Witness Statement, Dr. Bruce Clark, a Senior Vice President for Apotex Inc., testified that the Netherlands placed Apotex on import ban on behalf of the European Economic Area. Thus, assuming the Dutch authorities complied with Apotex's would-be rule, Apotex could readily provide evidence to that effect. Apotex has done no such thing, but rather avoids discussing any Dutch procedures that might be required. In that same paragraph, Dr. Clark also testified that the New Zealand authorities placed Apotex on import ban. Thus, it should be easy for Apotex to establish that the New Zealand authorities complied with Apotex's would-be rule. Again, Apotex does no such thing.

In the same paragraph, Dr. Clark also testified that the Australian authorities required Apotex to recall its products. Let's take a look at how Apotex itself characterized the reaction of the

15:04:31 Australian authorities.

Let's look at the first page of Exhibit C-95 on the screen, which is an e-mail from Apotex Australia to Dr. Jeremy Desai, Dr. Clark, and others. The e-mail memorializes a conversation Apotex Australia had with TGA, which stands for Therapeutic Goods Administration, the relevant Australian authority.

In the e-mail the Apotex Australia states that it was required to take certain actions by the Australian authorities. The e-mail states, in part, "These are the actions that we have to take, nonnegotiable." And what follows are two different nonnegotiable items.

We've highlighted the first two sentences of the second one which states, "We are to suspend all shipments of products manufactured by the Signet and Etobicoke sites for Australia with immediate effect. The suspension is to remain in place until Health Canada has completed its review of the Signet site."

There is no reference in the e-mail to the general procedural safeguards in Apotex's purported

15:06:11 four-prong rule that Apotex said was required by customary international law, nor is it anywhere in Apotex's briefs. It is fairly clear from the e-mail that they were not provided.

Nor does Apotex assert that Canadian law, something with which Apotex should be intimately familiar, provides such safeguards. If Canadian law did require Apotex's procedural safeguards be provided before the importation of adulterated drugs could be stopped, Apotex could easily establish as much in light of Canada's decision to block the importation of drugs from a U.S. company's facility in Ohio earlier this year discussed by my colleague, Mr. Bergman in his presentation.

Apotex sought to excuse its failure to provide State practice from the relevant context by arguing that to collect State practice would require "quite a bit of resources."

That's from Page 479 of Tuesday's transcript.

But that would not have been the case for the Netherlands, New Zealand, and Australia, with which Apotex had firsthand experiences. It could have

15:07:24 readily provided evidence of the legal processes these States provided to Apotex, if any actually were.

In light of this wholesale absence of State practice, Apotex decided to submit two French authorities on the eve of the hearing. As the Tribunal heard, Apotex justified this late submission by arguing that the United States had raised this lack of State practice for the first time in the Rejoinder.

You can see that on Pages 23, 25, 26, and 27 of Monday's transcript. The record reflects that the United States did, indeed, raise this in its Counter-Memorial in Paragraphs 366 and 367.

In any event, these authorities state--these French authorities state that for emergency situations, no legal process need be provided before measures are taken.

We would submit that the importation of the adulterated drugs is just such an emergency, and that, therefore, even these provisions undercut Apotex's position. And even if protecting the public health was not considered an emergency, general and consistent State practice cannot be proven by

15:08:51 submitting the practice of one State.

Moreover, Apotex has not provided any evidence of opinio juris with respect to these two French authorities. The Tribunal has no way of knowing whether France has adopted these provisions because it believes the provisions are required under customary international law or whether it simply believes the provisions are good policy.

To sum up on this point, in this claim, there is evidence of State practice from the relevant context, that context being the importation of the adulterated drugs. This State practice provided Apotex with an opportunity to help carry its burden of proving the State practice element of customary international law.

However, Apotex has avoided discussing this State practice. It is simply untenable for Apotex to argue for a rule of customary international law when the only State practice it has identified fails to support the rule it advances.

In light of the absence of any authorities from the relevant context, Apotex looks to Arbitral

Awards. Such decisions, of course, do not constitute State practice or opinio juris. In any event, as we have shown, relevant Arbitral Awards weigh in favor of United States's position, not Apotex's.

Indeed, Apotex has not identified a single Arbitral Award concluding that a State is required to apply the same procedural safeguards in every administrative decision regardless of context. Nor has it identified any Arbitral Award that has adopted Section 181 of the Restatement Second on the Foreign Relations Law of the United States as a rule of Minimum Standard of Treatment. Apotex would like this Tribunal to be the first.

Moreover, investor-State Tribunals do not sit retrospectively in judgment of a State's discretionary exercise of a sovereign power made rationally and in good faith. They recognize that it is not the role of an Arbitral Tribunal to substitute its view of the regulatory decision for the State's view. And yet, that is what Apotex is asking this Tribunal to do.

The ability to decide which drugs are adulterated in accordance with legal standards, the

cGMP regulations, is an important sovereign function for any State regulator of pharmaceutical drugs, and the decision to block the importation of drugs is a difficult discretionary exercise involving many complex factors.

A wide margin of appreciation in taking measures to protect the public health is appropriate before an investor-State Tribunal could find that the Minimum Standard of Treatment was violated. But here, no margin is even necessary, as FDA's decision was based on cGMP violations that Apotex did not even dispute. Finding no support in State practice and opinio juris or in Arbitral Awards, Apotex cites to a hodgepodge of Authority that has nothing to do with the kind of internal administrative decision making at issue in this case.

As we explained in our Rejoinder, as Authority for its would-be rule, Apotex relied on Authorities such as those discussing criminal law, the sanctity of contracts, domestic violence, and the placement of children. What was noticeably lacking is any Authority regarding the importation of drugs until

the French provisions appeared. One must ask why Apotex has omitted such Authorities when that is the subject matter of this claim.

In addition to this State practice from Apotex not being relevant, Apotex has barely addressed opinio juris for the practice it did submit. States have many laws, regulations, and practices. Simply because they exist does not mean that States believe all these laws, regulations, and practices are automatically transformed into international law.

For the second element of customary international law to be satisfied, evidence of opinio juris must be demonstrated. Apotex barely addressed opinio juris for the practice it had submitted.

In Paragraph 402 of the Reply, Apotex states that the types of Legal Authorities it has submitted, including State practice, national and international case law, Restatements of law, and legal scholarship are able to establish opinio juris. Just because these Authorities may, sometimes, serve as proof of opinio juris does not mean that they always do.

The content of the Authorities must be examined to see if opinio juris is addressed. But Apotex omits this step for most of the Authorities it cites. Most of Apotex's Authorities may be quickly dismissed because Apotex brings forth no evidence of opinio juris.

As the Glamis Tribunal stated, the evidence of such concordant practice undertaken out of a sense of legal obligation is exhibited in very few Authoritative sources--Treaty ratification language, statement of governments, Treaty practice, e.g., model BITs, and sometimes pleadings. Although one can readily identify the practice of States, it is usually very difficult to determine the intent behind those actions.

Looking to a Claimant to ascertain custom requires it to ascertain such intent, a complicated and particularly difficult task. In the context of arbitration, however, it is necessarily Claimant's place to establish a change in custom.

The last Apotex authority I'd like to discuss is Section 181 of the Restatement Second. Finding no

15:15:09 support in State practice, Apotex relies heavily on this section. However, by its express terms, Section 181 applies--sorry. If you'd give me a moment. I want to make sure I don't extend into the confidential information.

PRESIDENT VEEDER: Do you want us to go into closed session?

MR. BLANCK: Yes, I think that would be appropriate.

PRESIDENT VEEDER: Let's go into closed session.

SECRETARY TAYLOR: Session now closed.

15:15:52 CONFIDENTIAL PORTION

MR. BLANCK: I'll start again.

The last Apotex Authority I'd like to discuss is Section 181 of the Restatement Second. Finding no support in State practice, Apotex relies heavily on this section. However, by its express terms, Section 181 applies to trials or other proceedings. Section 181 does not purport to apply to all administrative decision making, just trials and other proceedings.

In this case, there was no proceeding. There could have been a proceeding if Apotex had invoked its right to a detention hearing for the products that the United States detained at the border, but it did not, and no proceeding took place. As such, Section 181 does not apply.

Now, Apotex has argued that the words "other proceeding" encompasses within its scope all administrative decisions that do not occur in an adjudicative context. I'd refer the Tribunal Page 474 of Tuesday's transcript. This is wrong. It is correct that some proceedings are adjudicative and

15:17:22 some are not. However, some administrative decisions are made outside the context of a proceeding. In fact, thousands of administrative decisions get made every day outside the context of a proceeding.

Section 181 does not purport to apply to administrative decisions not made through a proceeding, as was the case with the Import Alert. Section 181 simply does not apply here. Of course, even if a so-called proceeding had occurred here, under Apotex's newfound view of this section, not all four factors it identified are required under customary international law.

Apotex now agrees that the context will determine which factors are required, but it has not provided any standards for the Tribunal, States, or Claimants, to evaluate this would-be rule. There are no standards setting forth what Apotex's affirmative case is, what factors must be proven under what circumstances, and why.

Under Apotex's current view, there is no way that a State would know how it could comply with international law when making administrative

15:18:35 decisions.

Under Apotex's third would-be rule, Claimants and States alike would be left groping in the dark to determine what might or might not be required by the Minimum Standard of Treatment. For example, Apotex argued at Page 476 of Tuesday's transcript that: If there is evidence of imminent harm, then a State may provide legal process after the Measure is adopted. It cited no Authority for this proposition, nor will you find this proposition in Apotex's Memorial or Reply. It simply a new shift in Apotex's position that it made at the Hearing. What type of threats might trigger this new exception? How imminent must the threat be? How intrusive a Measure may the State take? Apotex provides no answer to these questions.

Another argument advanced for the first time at the hearing was what I referred to earlier as the "severity of the consequences" prong, which Apotex discussed at Page 479 of Tuesday's transcript. There, Apotex argues that: The more severe the consequences to the alien, the more due process must be applied.

You won't find that being mentioned as a

15:19:55 factor in the Memorial or Reply, but what does this mean for a State in practice? How will a State know whether it is complying with international law in all the many administrative decisions it makes? Apotex's would-be rule provides no guidance.

Moreover, as we noted in our Rejoinder, Section 181 lists eight factors, not four. In its Reply, Apotex had not provided any explanation as to why it viewed four of them being required and the other four merited no discussion. On Tuesday--and I'll refer the Tribunal to Page 470 of the transcript--Apotex argued that it had omitted these four factors because they weren't relevant. It offered no support for that proposition. In fact, these four factors--these four excluded factors would support a conclusion that the United States provided Apotex with a fair process.

For example, one of the factors is whether the Alien was allowed to consult with counsel. In this case Apotex did, in fact, consult with very experienced counsel. Thus, this factor was satisfied. Apparently, factors are irrelevant if they cut against

15:21:11 Apotex's arguments.

Third, even if all four of the cherry-picked factors did form Black Letter Law, the United States complied with all these factors, as I will discuss in more detail in just a moment. But for the moment, I will just note that Section 181 does not contain a temporal element. In other words, Section 181 does not state when the procedural safeguards listed by Section 181 are to occur. There is simply no requirement that these safeguards occur before a decision is made for the terms of Section 181 to be satisfied. Some of the factors refer to reasonable opportunities, although that provides no standards that could guide a State.

In sum, none of the Authorities relied upon by Apotex establish that State practice and opinio juris have crystallized in a rule of customary international law that requires the array of legal processes envisioned by Apotex before a State engages in administrative decision making, including in the realm of halting the importation of the adulterated drugs.

15:22:28 Because Apotex has not carried its burden of establishing that any such rules exist, its claim under Article 1105(1) must be dismissed.

MR. BLANCK: You can bring the feed back on. I apologize. I cut it too early. You can bring it back on now and I'll stop briefly.

PRESIDENT VEEDER: Keep going.

MR. BLANCK: I see.

The first factor from Apotex's would-be rule is that the State must provide the exporter with an impartial administrative authority. The United States did so. We would note that Apotex has not set forth any facts even alleging bias or conflict of interest on the FDA's part.

For example, Apotex has not alleged that any FDA decision maker owned stock in an Apotex competitor. Apotex does not allege that any FDA employee had previously been fired by Apotex and held a grudge. Instead of providing any evidence of partiality, Apotex has simply argued that CDER alone should not be allowed to make a decision about an Import Alert.

15:23:51 As a factual matter, that is not what happened, but even if it had, that would not mean CDER was partial. Section 181 states that an impartial administrative authority--one such authority--is to be provided." CDER qualifies as such an authority. There is no requirement in Section 181 that more than one impartial authority be provided.

The next factor in Apotex's would-be rule is whether the State provided the exporter with ample information on the nature of the enforcement action.

In Paragraph 448 of its Reply, Apotex claimed that FDA never presented Apotex with reasons for Import Alert. Ms. Weil repeated this allegation on Page 501 of Tuesday's transcript and Mr. Legum did, as well, on Page 518 of the transcript.

However, on Day 1 of the Hearing, Mr. Hay stated that FDA did explain the reasons for the Import Alert in a phone call with Apotex on September 3. That can be found on Page 106 of the transcript.

As Mr. Hay explained, those reasons were significant cGMP violations at Signet, and the Warning Letter for Etobicoke, which, of course, also referred

to cGMP violations.

I'd refer you to the minutes from FDA-Apotex conference call, which is Exhibit R-45. As you can see, the minutes state that FDA's Mr. Edwin Rivera-Martinez explained that since the Etobicoke site received a Warning Letter and significant cGMP violations were found during the Signet inspection, August, an Import Alert was appropriate.

Just as one would expect, in the first conversation the FDA had with Apotex after issuance of the Import Alert, FDA informed Apotex of the reasons for the Import Alert. And as Ms. Cate noted earlier today, the FDA repeatedly explained that reasons for the Import Alert were Apotex's cGMP violations.

Moreover, when FDA detains items at the border without physical examination because of GMP violations, it provides notices that explicitly provide the reason.

I'd like to refer to an example of one such notice, which is part of Exhibit R-44. This is a Notice of Detention for one of the Apotex's items that gave rise to the claim. And as you can see on Page 2

of the Notice, which I'll read, it explicitly states, "It appears that the methods used in, or the facilities or controls used for manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with Current Good Manufacturing Practices." The notice clearly states that cGMP violations are the reason for the detention.

Additionally, on September 11, 2009, just eight days after the conference call, Apotex and FDA held a meeting where FDA once again noted that Apotex's cGMP violations were the source of its concern. The PowerPoint presentation FDA used at this meeting is Exhibit C-93. And I would direct the Tribunal to Slides 4-6 for FDA's cGMP concerns.

The call on September 3 and the meeting on September 11 were not the only times FDA communicated the cGMP problems to Apotex. As Apotex noted in Paragraphs 493 and 483 of its Reply, FDA and Apotex engaged in continuous contact through meetings, telephone conferences, and letters.

Now, on Tuesday, on Page 503 of the

transcript, Apotex says that these continuous discussions were forward-looking, not backward-looking and, thus, did not involve a discussion of the reasons for the Import Alert. It offers no support for this proposition.

Mr. President, I have now finished discussing all confidential information.

PRESIDENT VEEDER: Let's go back on the record. So open session. Thank you.

NONCONFIDENTIAL PORTION

MR. BLANCK: Thank you, Mr. President.

Now on Tuesday, on Page 503 of the transcript, Apotex says these discussions were forward-looking, not backward-looking and, thus, did not involve a discussion of the reasons for the Import Alert. It offers no support for this proposition, nor does it explain how forward-looking discussions explaining what Apotex needed to do to come into compliance and off of the Import Alert could occur without a discussion of the cGMP violations that were the reasons for the Import Alert. This statement is not credible.

The third and fourth factors of Apotex's would-be rule are that the State provide the exporter with reasonable opportunities to contest evidence and to obtain and present witnesses and evidence. The legal process provided in U.S. law provided all these opportunities through a variety of different legal procedures. Apotex could have challenged FDA's decisions through four different legal avenues, which are highlighted on the screen.

1508

15:29:58 First, Apotex could have invoked its right to a Detention Hearing in the district that detained Apotex's exports. Second, it could have appealed any FDA decision to the supervisor of the FDA employee who made the decision. Third, it could have filed a Citizen's Petition regarding any FDA decision which would have placed the issue before the FDA commissioner or her delegee. And, finally, it could have used--it could have filed suit under the Administrative Procedures Act.

Apotex pursued none of this legal process. Instead, it agreed with the FDA concerns and hired consultants to fix the problems. These consultants also found numerous cGMP problems. And it's against this backdrop that I'd like to turn to Apotex's contention that it did not have to pursue any of this process because such process was ineffective and the Respondent, not the Claimant, bears the burden of proving that the legal process, ignored by the Claimant, would have been effective.

I would note up front that Authorities such as the Diallo case are not relevant since this is not

1509

15:31:12 a diplomatic protection case that involves the exhaustion of local remedies. But even if this case presented the issue of exhaustion of local remedies by analogy, Apotex has misstated both who has the burden of proving the exhaustion of remedies and the standard of proof. It also contradicts the very position Apotex took on both these issues in the first two NAFTA arbitrations Apotex brought against the United States.

The correct standard for exhaustion of local remedies is obvious futility, and the burden is on the Claimant to show this standard is met for any legal process it chose not to exhaust. As we noted in Paragraph 329 of our Rejoinder, in both of Apotex's briefs in the first two arbitrations, it argued that obvious futility was the correct standard when the Parties were discussing exhaustion of local remedies in the judicial finality context. Additionally, at the hearing in those arbitrations, Apotex acknowledged that it had the burden of proving this standard.

On Day 1 of the hearing, in attempting to rebut the United States's local remedies argument,

1510

15:32:29 Apotex stated, "I don't think there's a lot of dispute about what the final--finality requirement is. The major dispute seems to be: Did Apotex meet it?"

Thus, Apotex explicitly framed the question as whether it had met its burden, not whether the United States had met the burden of proof. And as we note in Paragraph 329 of our Rejoinder, as Apotex correctly conceded on Tuesday at Page 510 of the transcript, that is the same way the Tribunal applied the burden of proof as well. And of course, the obvious futility standard is what the Tribunal in those arbitrations applied in its Award on Paragraph 284.

But now Apotex has changed tack. In Apotex's newfound view, a Claimant can bring a claim for the alleged violation of a general rule of due process after having ignored all the legal process provided in the Respondent's law, and then claim that the burden is on the Respondent to prove that the ignored legal process would have been effective had the Claimant actually utilized it.

The breadth of such a rule would be stunning.

1511

15:33:46 It effectively reads out the third and fourth factors of Section 181 from Apotex's would-be due process rule when it comes to proving a Claimant's case. The four prongs cherry-picked from the body of Section 181 thus drop to two.

This turns international law on its head. If there really were a general four-prong rule of due process--which Apotex has not established--then consistent with standard rules of burden of proof, the Claimant has the burden of establishing each and every element of its affirmative case. And, here, the third and fourth prongs of Apotex's would-be rule, at least as stated in the Reply, relate to local remedies.

Thus, under Apotex's own rule, it must prove that the legal process afforded to it by U.S. law did not provide a reasonable opportunity to contest the evidence against it, nor to obtain or present Witnesses and evidence in its own behalf. It is not the burden of the United States to disprove these parts of Apotex's affirmative case.

Apotex attempts to distinguish the Apotex I and II Award by arguing that it should be limited to

15:35:03 fair and equitable treatment claims involving a denial of justice based on court acts. That can be found on Page 509-511 of Tuesday's transcript. And specifically on Page 509 of the transcript, Apotex argues that because local remedies are part of the substantive claim of denial of justice, the Tribunal should not look to the Apotex I and II Award. But that is not a distinction; it's a similarity.

In this case, for Apotex to make out its substantive claim, it must prove, under its theory, some deprivation of procedural safeguard or safeguards. It's not clear what that might be under its new flexible would-be rule, but certainly there must be some affirmative case for it to make out. Consistent with normal rules of burden of proof, the Claimant has the burden of proving its affirmative case.

Moreover, any claim involving due process--such as Apotex claims here--is a claim alleging failure of legal process. Thus, both Apotex's own argument in Apotex I and II as well as the Award weigh in favor of a conclusion that the

15:36:18 burden of proving obvious futility is on the Claimants.

As the United States demonstrated in its Rejoinder, the obvious futility standard is a high one and cannot be satisfied by mere supposition, and it certainly cannot be satisfied when any futility that might exist exists because the Claimant agreed with the Respondents on the Merits of the issue contemporaneous to the events that gave rise to the claim, as is the case here.

In any event, Apotex concedes that the United States made available the three administrative local remedies that we identified: The district hearing, the administrative appeal, and the Citizen's Petition.

The primary method Apotex had to challenge the FDA decision to refuse admission of Apotex's products to the United States was a detention hearing in the district that he detained the products. We discuss this in some detail in the Rejoinder from paragraphs 342-345, and I will not rehash those points now.

I will note the following points: On

15:37:26 Tuesday, at pages 485-486 of the transcript, and in the supplement to its Reply, Apotex argued that mistakes and misunderstandings resulted in the Import Alert. If Apotex really believed that was the case, the district hearing was its opportunity to correct these alleged mistakes and misunderstands. It never did so.

Moreover, we note the irony of Apotex's argument here. Although Apotex claimed that there should be a right to a hearing before the decision to issue the Import Alert was made, it never utilized the opportunity that it did have.

The next legal avenue Apotex had to challenge the FDA decision was the administrative appeals process, which I just referred to. FDA regulations provide that an interested person outside the FDA may raise for review any decision by an FDA employee with the supervisor of that employee. Thus, Apotex could have by bypassed the detention hearing procedure and utilized the appeals process to challenge any FDA decision, such as the Import Alert or the cGMP determinations. But Apotex never did so.

15:38:41 This week, at the hearing, Apotex made a series of arguments about the supposed ineffectiveness of this hearing--of this process, all which of are wrong, as we explained in our Rejoinder from Paragraphs 346-352. And I will not repeat those arguments here.

The next legal avenue Apotex could have taken to dispute FDA's decision was a Citizen's Petition. Under FDA regulations, Apotex could have petitioned the FDA Commissioner or her delegee to order, take, or refrain from taking any administrative action. Again, Apotex has made a series of criticisms of this mechanism which we respond to in Paragraphs 353-362 of the Rejoinder, and which I won't repeat here.

There is one statement by Apotex that I would like to clarify. Apotex stated at Page 517 of Tuesday's transcript that "The U.S. fails to recognize that the Commissioner has delegated the authority to issue decisions on Citizen's Petitions right back to CDER."

But as a review of our Exhibit R-184 shows, whether and to whom a Citizen's Petition is delegated

depends on the subject matter of the petition. For example, a challenge to CDER impartiality or Import Alerts generally would not have gone to CDER. We refer the Tribunal to Paragraph 360 of the Rejoinder, where we refer to the Commissioner's delegees and the delegation.

Apotex has argued that these administrative remedies were not effective because FDA allegedly told them that only a re-inspection could remove them from the Import Alert. The United States addresses these arguments in Paragraph 358 of its Rejoinder. Apotex did not respond to these arguments so the United States will rest on these points.

But even if U.S. law had not afforded Apotex any of these three administrative remedies, Apotex could have attempted to bring a claim in U.S. court under the Administrative Procedures Act, also known as the APA. In fact, Apotex could have attempted to bring two different types of APA suits. First, if Apotex believed that FDA the was taking too long to re-inspect its facilities or remove it from the Import Alert or to approve its ANDAs, it could have attempted

to bring a suit for unreasonable delay for any of these disputes under Section 706, Paragraph 1, of the APA.

In Paragraph 363 of the Rejoinder, we noted that Apotex has previously brought an unreasonable delay suit against the FDA for alleged delay in making a compliance determination for certain Apotex facilities, as well as the resulting delay in approving two of Apotex's ANDAs.

In September of 2011, Apotex was threatening to do so again, this time because FDA was allegedly not conducting pre-approval inspections, or PAIs, as quickly at Apotex would have liked. That threat for the new lawsuit can be found in Exhibit R-201, Bates Number US004533. Because Apotex did not respond to our points on unreasonable delay lawsuits during its presentation, we will not discuss them further.

The second type of APA suit that Apotex could have brought was one challenging the Import Alert itself. Apotex has correctly informed the Tribunal--and the United States has acknowledged--that the U.S. Executive Branch has taken the position that

these types of suits are not properly entertained by the courts. But what Apotex did not tell the Tribunal is that Apotex has taken the position that these types of suits are properly entertained by the courts.

On May 4, 2011, prior to Apotex being removed from the Import Alert, Apotex's lawyer threatened to sue the FDA. I'd refer to an e-mail which is Exhibit R-194. This e-mail is from a lawyer Apotex hired to work on this matter to Mr. Tyler, who was then FDA's top lawyer.

PRESIDENT VEEDER: For accuracy. That's the 3rd of May, isn't it? You said 4th of May.

MR. BLANCK: Yes, that's correct, I apologize, Mr. President.

On May 3, 2011--I'll read the e-mail in pertinent part, which states: "Ralph, first I want to thank you for your help in this matter. I also wanted to let you know that our client is very frustrated and has authorized us to work on bringing a lawsuit. I know from our exchange last year that CDER believes that it cannot be sued for this. I do not agree."

That pretty much sums up the position of the

Parties. It was and is the position of the United States Executive Branch that a lawsuit may not be properly entertained by a court under Paragraph 2 of Section 706 of the APA to challenge an Import Alert. Our position remains the same. However, as we noted in our brief, the courts do not always rule in favor of the Executive Branch.

What is noteworthy is that Apotex has, once again, changed its position just for the purposes of this arbitration. While the events relevant to this claim were occurring, Apotex was telling the FDA that it had authority to bring a lawsuit. But in this arbitration, Apotex claims just the opposite.

For the last part of my presentation, I'd like to turn to the implications for States if the Tribunal were to create a new rule of customary international law as set forth by Apotex.

If Apotex's argument is correct, if international law really required States to engage in some unknown combination of procedural safeguards for every administrative decision it made, even those made outside the context of general administrative decision

15:45:45 making, the results would be stunning. Government decision making would grind to a halt. Resources would be wasted and States would not be able to act quickly to protect the public.

With respect to public health and safety, there is a good reason that customary international law does not require prior notice or a prior right to contest the State's decision before a State may take administrative action, including the halting of a company's export of adulterated drugs into its territory.

If a State's hands were tied in this way, an exporter could engage in dispute resolution, thereby preventing a State from acting while simultaneously flooding the market with adulterated drugs.

Apotex is arguing for a rule of customary international law and, as such, the rule would apply to every State every time they need to engage in a whole host of administrative actions aimed at protecting the safety and well-being of the public.

Much as it would be nice to envision a world where every exporter acts in the interest of public

15:46:53 health in every situation, that is not the world we live in. States cannot cross their fingers and hope for the best, and international law does not require them to do so.

In conclusion, Apotex's claim under Article 1105 fails because its allegations relate to treatment of investors, not investments, and thus, do not fall within the scope of Article 1105(1). It also fails because Apotex has failed to prove State practice or opinio juris to support a rule of customary international law that would require general due process in administrative decision making.

Mr. President, Members of the Tribunal, unless you have further questions, I would ask that you call on my colleague, Mr. Bigge, who will address Apotex's allegations regarding the MFN clause and the Jamaica BIT.

PRESIDENT VEEDER: Thank you very much, indeed. Just looking at whether we can have five minutes for a short break, or whether we have time.

MS. GROSH: Mr. President, if we have time, why don't take 10 minutes?

15:48:09 PRESIDENT VEEDER: Our Court Reporter has been struggling through this without a single complaint. Let's take 5 minutes for the shorthand writer.

MS. GROSH: Very good. Thanks.

(Brief recess.)

PRESIDENT VEEDER: Let's resume.

MR. BIGGE: Thank you. Mr. President, Mr. Rowley, Mr. Crook, I have the pleasure of delivering our last presentation of the day, and it is a comparatively brief one.

Apotex's reliance on the "effective means" clause in the U.S.-Jamaica Bilateral Investment Treaty is misplaced. First, Apotex has failed to show that it would be entitled to better treatment under the U.S.-Jamaica BIT than under the NAFTA. Neither Treaty requires due process with respect to internal administrative decision making, nor has Apotex attempted to show that a comparator in like circumstances actually received or would have received better treatment.

Second, Apotex failed to utilize the means

15:57:22 that were available to it and, thus, cannot demonstrate their ineffectiveness.

And third, assuming Apotex had met the requirements to invoke Article 1103, Apotex's claim still fails because it had no claim to assert or right to enforce under the U.S.-Jamaica BIT. I will address these three points, in turn.

Apotex's initial "effective means" claim was very narrow: In its Memorial at Paragraph 483, Apotex asserts that the "effective means" provision of the U.S.-Jamaica BIT was violated because in Apotex's view, Apotex--"the imposition of the Import Alert was the result of administrative proceedings during which it had no possibility to be heard and defend itself."

That is, Apotex claims that it had a right to be heard prior to FDA's internal administrative decision to add Apotex's Etobicoke and Signet facilities to the Import Alert. This is, of course, very similar to the claim Apotex asserts under Article 1105. The argument fares no better under Article 1103 for one simple reason: Apotex cannot prove that it would have received better treatment

15:58:44 under the U.S.-Jamaica BIT than it would under the NAFTA. Neither Article 1105 nor the "effective means" clause in the Jamaica BIT requires the Government to provide due process in the context of an internal temporary import advisory.

An examination of the "effective means" clause in the U.S.-Jamaica BIT, Article II(6) of that Treaty makes clear its limitation to adjudicatory proceedings. The clause reads--and it's on the screen--"Each Party shall provide effective means of asserting claims and enforcing rights with respect to investments, investment agreements, and investment authorizations granted by a Party's foreign investment authority."

Logically the phrase "means of asserting claims and enforcing rights" refers to adjudicatory proceedings because that's where claims can be asserted and rights can be enforced.

In his argument on Tuesday--and this is at Transcript Pages 529 and 530--Mr. Legum said that this view is "nonsensical because rights exist outside of courts." And this is, of course, true; rights do

16:00:08 exist outside of courts, but rights are enforced through adjudicatory proceedings. By the "effective means" clause, the United States was not committing to refrain from making internal decisions without providing a hearing to investors, rather, the United States was committing itself to providing effective means for enforcing rights; that is, courts, Administrative Tribunals, and other adjudicatory processes in which investors can bring claims with respect to their investments. This interpretation is not derived just from the plain meaning of the words of the Treaty. It is supported by the history of the "effective means" provision.

According to Professor Kenneth Vandevelde, whose text we have put in the record at Exhibit RLA-286, the "effective means" clause in the U.S. BITs, early Bilateral Investment Treaties, was derived from judicial access provisions in U.S., Friendship, Commerce, and Navigation treaties.

Apotex's attempts to invoke the arbitral decisions in Chevron v. Ecuador and White Industries v. India to support its position is unavailing. In

16:01:28 those cases, the Tribunal's differentiated between the effective-means clauses in the relevant treaties and the denial of justice standard under customary international law. Of course, Apotex does not discuss the Duke Energy v. Ecuador Award, which we have put in the record at RLA-267(a) in which the Tribunal found just the opposite; that "effective means" is merely a component of the customary international law denial of justice standard.

The United States takes no position on this issue in this case because Apotex's argument is a red herring. The Tribunal does not have to decide whether "effective means" is equivalent to the denial of justice or is a different standard. This is because both the Chevron/White Industries standard and the Duke Energy standard only measured the effectiveness of adjudicatory proceedings. Chevron, White Industries, and Duke Energy all explored the "effective means" standard in the context of delays in the host State's judicial system.

None of these cases support Apotex's novel proposition that a State has to consult with, much

16:02:44 less provide a hearing for, an investor prior to making an internal non-final decision that might impact the investment.

Thus, whatever interpretive standards for "effective means" one chooses, the result is the same. The U.S.-Jamaica BIT provides no better treatment for Apotex than NAFTA Article 1105 because the "effective means" clause applies to adjudicatory proceedings which are not at issue here.

Apotex has also failed to demonstrate that any comparator in like circumstances actually received or would have received better treatment. We've discussed a number of other companies that were placed on the Import Alert during the course of this hearing: Ranbaxy, Claris, Aurobindo, et cetera, and Apotex has not shown that any of them were provided or entitled to any type of pre-decisional hearing before FDA made the decision to place the companies on Import Alert.

Of course, when these companies' products including Apotex's, were detained at the border, they could have pursued their rights at a detention hearing or used other available challenge mechanisms to

1528

16:03:57 challenge the agency action.

Apotex added a new argument in its Reply that the post-decision challenge mechanisms available to it, the detention hearing, the Citizen's Petition, et cetera, were ineffective. This is in the Reply at Paragraph 527. But this argument, like the previous argument, fails because as we've established, Apotex did not attempt to utilize any of these several avenues for challenge.

The White Industries Tribunal, in Exhibit CLA-77 at Paragraph 11.3.2, cited to the Chevron Award for the proposition that to pursue an "effective means" claim, Claimants must have at least "adequately utilized the means available to them." And that language is on the screen. Here Apotex admits that it did not even try to utilize any of the means it now claims were ineffective.

This failure rightfully dooms Apotex's "effective means" argument. For example, at Paragraph 61 of their Second Report, Mr. Bradshaw and Mr. Johnson admit that under the relevant regulation, the Citizen Petition process requires FDA to furnish a

1529

16:05:19 response to each petitioner within 180 days of receipt of the petition. They nonetheless argue that this requirement is fleeting because FDA may provide only tentative responses. Thus, they conclude--and this is on the screen--"in effect, FDA can (and often does) decide not to decide whether a Citizen Petition should be granted." Note the wording here: Not "always" or "even most of the time" but "often."

Just because FDA sometimes offers only tentative responses on a Citizen Petition does not render that means ineffective in all cases, and it certainly does not mean that FDA would have delayed taking action on a petition filed by Apotex. Indeed, Mr. Vodra explained in his Report at Paragraph 103 how he has successfully used the Citizen Petition to obtain redress for his clients. He writes," In fact, I have frequently recommended to clients the use of Citizen Petitions, and they have often received positive results." It is for this reason that, under Chevron and White Industries, Apotex at least had to try the Citizen Petition route before claiming it to be ineffective.

1530

16:06:41 As Mr. Vodra succinctly stated yesterday in his testimony--and this is at Page 1104 of the transcript--"the real problem with Apotex's ineffectiveness argument is that Apotex conflates facts and law." Apotex claims that the challenge mechanisms were futile because any claim Apotex might have asserted would have failed. But simply because Apotex's particular claim would fail on the facts does not mean that the legal remedy itself is ineffective. And this leads me to my final argument.

Apotex's assertion that the United States did not provide effective means for asserting claims and enforcing rights fails because Apotex had neither claims to assert nor rights to enforce.

As we have made clear throughout these hearings, Apotex cannot seriously dispute even in this arbitration, that it had significant cGMP problems. Apotex does not and cannot dispute that under long-standing U.S. law, law Apotex's does not challenge, products manufactured at facilities that are not cGMP compliant are deemed to be adulterated. Apotex does not dispute that under well established

1531

16:07:57 U.S. law, law that is mirrored in Canada and in many other countries, the United States can prevent adulterated drugs from crossing its borders and entering its marketplace.

Therefore, Apotex had no legal claim to assert. Its products were rightfully subject to detention and refusal under existing US laws and regulations that Apotex does not challenge. It similarly had no right to enforce both because of its admitted cGMP violations and because, again, under very well established U.S. law that we discussed in our Rejoinder at Paragraph 297, there is no right to import products from foreign countries into the U.S. market.

Mr. President, Members of the Tribunal, this concludes my presentation on Apotex's U.S.-Jamaica BIT argument.

PRESIDENT VEEDER: Thank you very much. We have no questions at this stage.

MS. GROSH: Mr. President, Members of the Tribunal, that concludes the United States's Presentation-in-Chief. We were very mindful of the

tight timing today, and we also assumed that the Tribunal may have questions to pose to the Parties. So we did not prepare concluding remarks, and we'll reserve those for our closing on Monday.

PRESIDENT VEEDER: Of course. What we're minded to do--you've given us both a lot to think about--is to send you an e-mail probably tomorrow. It will have certain topics, rather than questions, that we'd like you to address on Monday, if you can.

Obviously, you must take your own course in regard to what you want to say to us by way of your respective replies, but we thought it might be helpful if we steered in a few directions where we thought it might be more helpful to address that in more detail than other otherwise. But we haven't got the questions or topic quite ready now to give to you. We'll do that tomorrow.

That, I think, is all we want to say about that at the moment. We'll see, obviously, all of you at 9:00 Monday morning. You've given us a lot to think about and read about over the weekend, but I hope you have a rest as well.

Is there anything else we need to address? We ask the Claimants first.

MR. LEGUM: No, Mr. President.

PRESIDENT VEEDER: And the Respondent?

MS. GROSH: No, Mr. President.

PRESIDENT VEEDER: Thank you very much. You've worked very hard this week. I hope you have some rest this weekend. Until Monday.

(Whereupon, at 4:10 p.m., the hearing was adjourned until 9:00 a .m. the following day.)

CERTIFICATE OF REPORTER

I, Dawn K. Larson, RDR, Court Reporter, do hereby certify that the foregoing proceedings were stenographically recorded by me and thereafter reduced to typewritten form by computer-assisted transcription under my direction and supervision; and that the foregoing transcript is a true and accurate record of the proceedings.

I further certify that I am neither counsel for, related to, nor employed by any of the parties to this action in this proceeding, nor financially or otherwise interested in the outcome of this litigation.

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DAWN K. LARSON